

UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF OHIO

CITY OF CLEVELAND, OHIO,

Plaintiff,

v.

ELI LILLY AND COMPANY;  
NOVO NORDISK INC.;  
SANOFI-AVENTIS U.S. LLC;  
EVERNORTH HEALTH, INC.  
(FORMERLY EXPRESS SCRIPTS  
HOLDING COMPANY);  
EXPRESS SCRIPTS, INC.;  
EXPRESS SCRIPTS ADMINISTRATORS,  
LLC;  
MEDCO HEALTH SOLUTIONS, INC.;  
ESI MAIL PHARMACY SERVICES, INC.;  
EXPRESS SCRIPTS PHARMACY, INC.;  
CVS HEALTH CORPORATION;  
CVS PHARMACY, INC;  
CAREMARK RX, LLC;  
CAREMARK PCS HEALTH, LLC;  
CAREMARK, LLC;  
UNITEDHEALTH GROUP, INC.;  
OPTUM, INC.;  
OPTUMRX INC.;  
OPTUMINSIGHT, INC.,

Defendants.

Case No.:

Judge:

Magistrate Judge:

**Jury Trial Demanded**

COMPLAINT

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Plaintiff the City of Cleveland, Ohio, brings this action against the above-named Defendants and alleges as follows:

## I. INTRODUCTION

1. The cost of diabetes medications has skyrocketed over the past 20 years. Over that time, the average cost of consumer goods and services has almost doubled. The cost of some diabetes medications has risen more than tenfold. These price increases are not due to the rising cost of goods, production costs, investment in research and development, or competitive market forces. These price increases have been engineered by Defendants to exponentially increase their profits at the expense of payors, like Plaintiff, and their plan members. It is a multibillion-dollar industry.

2. Diabetes is widespread. According to the American Diabetes Association, the total estimated cost of diabetes in the U.S. in 2017 was \$327 billion.

3. In Ohio alone, diabetes costs an estimated \$12.3 billion per year in direct medical expenses and more than one million Ohioans—12.1% of the adult population—have diabetes.<sup>1</sup> In Cleveland, approximately 16.8% of adults have diagnosed diabetes.<sup>2</sup>

4. Defendants Eli Lilly, Novo Nordisk, and Sanofi (collectively, the “Manufacturer Defendants” or “Manufacturers”) manufacture most insulins and other diabetes medications available in the United States. In 2020—as in years past—the three Manufacturer Defendants controlled 92% (by volume) and 96% (by revenue) of the global market for diabetes drugs.

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<sup>1</sup> See American Diabetes Association, *The Burden of Diabetes in Ohio* (Apr. 2022), [https://diabetes.org/sites/default/files/2022-04/ADV\\_2022\\_State\\_Fact\\_sheets\\_all\\_rev\\_OH-4-4-22.pdf](https://diabetes.org/sites/default/files/2022-04/ADV_2022_State_Fact_sheets_all_rev_OH-4-4-22.pdf) (last visited June 28, 2023).

<sup>2</sup> CDC releases interactive neighborhood-level health data for 500 cities, including Cleveland (Mar. 2017), [https://www.cleveland.com/healthfit/2017/03/cdc\\_releases\\_interactive\\_neighborhood-level\\_health\\_data\\_for\\_500\\_cities\\_including\\_cleveland.html](https://www.cleveland.com/healthfit/2017/03/cdc_releases_interactive_neighborhood-level_health_data_for_500_cities_including_cleveland.html).

5. Defendants CVS Caremark, Express Scripts, and OptumRx (collectively, the “PBM Defendants”) are pharmacy benefit managers that work in concert with the Manufacturer Defendants to dictate the availability and price of the at-issue drugs for most of the U.S. market.<sup>3</sup> The PBM Defendants are, at once, (1) the three largest PBMs in the United States (controlling more than 80% of the PBM market); (2) the largest pharmacies in the United States (comprising three of the top five dispensing pharmacies in the U.S.); and (3) housed within the same corporate families as three of the largest insurance companies in the United States—Aetna (CVS Health), Cigna (Express Scripts), and UnitedHealthcare (OptumRx).

6. These Defendant corporate conglomerates sit at 4th (CVS Health), 5th (UnitedHealth Group), and 12th (Cigna) on the Fortune 500 list as of year-end 2022.

**Figure 1: PBMs & PBM-Affiliated Insurers**

<b>PBMs</b>	<b>PBM-Affiliated Insurer</b>
CVS	Aetna
Express Scripts	Cigna
Optum	UnitedHealthcare

7. For transactions where the PBMs control the insurer, the PBM, and the pharmacy (e.g., Aetna–Caremark–CVS Pharmacy)—these middlemen capture as much as half of the money spent on each insulin prescription (up from 25% in 2014), even though they contribute nothing to the development, manufacture, or innovation of the drugs.

8. The PBMs establish national formulary offerings (i.e., approved drug lists) that, among other things, set the baseline for which diabetes medications are covered and not covered by nearly every payor in the United States, including those in Cleveland.

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<sup>3</sup> The “at-issue drugs” or “at-issue medications” are: Apidra, Basaglar, Humalog, Humulin N, Humulin R, Humulin R 500, Humulin 70/30, Lantus, Levemir, Novolin N, Novolin R, Novolin 70/30, Novolog, Ozempic, Soliqua, Toujeo, Tresiba, Trulicity, and Victoza.

9. The Manufacturers and PBMs understand that the PBMs' national formularies drive drug utilization. The more accessible a drug is on the PBMs' national formularies, the more that drug will be purchased throughout the United States. Conversely, exclusion of a drug from one or more of the PBMs' formularies can render the drug virtually inaccessible for millions of covered persons.

10. Given the PBMs' market power and the crucial role their standard formularies play in the pharmaceutical pricing chain, both Defendant groups understand that the PBM Defendants wield enormous influence over drug prices and purchasing behavior.

11. The unfair and deceptive conspiracy at the root of this Complaint—the “Insulin Pricing Scheme”—was borne from this mutual understanding.

12. The Manufacturers set the initial list price (wholesale price) for their respective insulin medications. Over the last 20 years, list prices have sharply increased in lockstep, even though the cost to produce these drugs decreased during that period.

13. The Manufacturer Defendants have in tandem increased the prices of their insulins up to 1000%, even though production costs decreased during that period.

14. Insulins that today cost the Manufacturers as little as \$2 per vial to produce were priced at \$20 per vial in the 1990s, but now range in price from \$300 to \$700.

15. The Manufacturer Defendants have in tandem increased the prices of their insulins up to 1000%, taking the same increase down to the decimal point within a few days of one another and, according to a U.S. Senate Finance Committee investigation, “sometimes mirroring” one another in “days or even hours.”<sup>4</sup> Figure 2 shows the rate at

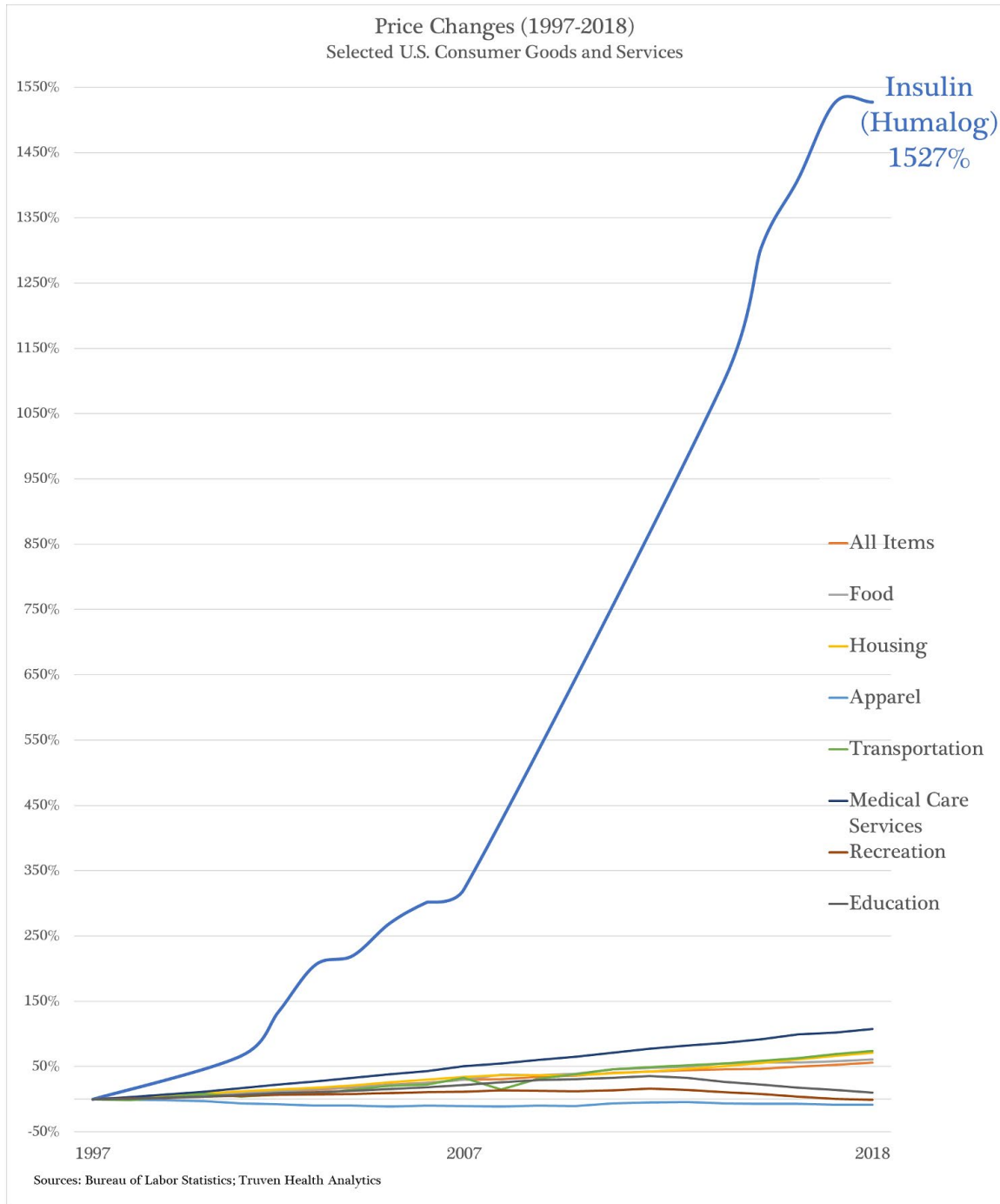
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<sup>4</sup> Charles E. Grassley & Ron Wyden, *Staff Report on Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug*, Sen. Fin. Comm., at 6, 54, 55 (Jan. 2021), <https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20FINAL%201>). Pdf (hereinafter “Grassley & Wyden” or “Senate Insulin Report”).



which Defendant Eli Lilly raised the list price of its analog insulin, Humalog, compared to the rate of inflation for other consumer goods and services from 1997-2018.

**Figure 2: Price Increase of Insulin vs. Selected Consumer Goods.  
1997-2018**



16. Today's exorbitant prices starkly contrast with insulin's origins. The inventors sold the original patent for \$1 to ensure that the medication would remain affordable. Today, insulin is the poster child for skyrocketing pharmaceutical prices.

17. Little about these medications has changed over the past hundred years; today's \$350 insulin is the same product Defendants once sold for \$20 in the 1990s.

*How the Insulin Pricing Scheme Works*

18. In the simplest terms, there are three important participants in the insulin medication chain.

- a. *The City of Cleveland*. During the relevant period, Plaintiff operated health plans for its employees and their dependents. The plan includes pharmacy benefits; meaning Plaintiff purchased the at-issue drugs for its beneficiaries. Operators of self-funded plans, like Plaintiff, may be referred to as payors or plan sponsors (or PBM "clients").
- a. *Pharmacy Benefit Managers*. Payors routinely engage pharmacy benefit managers to manage their prescription benefits, which includes negotiating prices with drug manufacturers and (ostensibly) helping payors manage drug spending. Each pharmacy benefit manager—including the three PBMs here—maintains a formulary—a list of covered medications. A pharmacy benefit manager's power to include or exclude a drug from its formulary theoretically should incentivize manufacturers to lower their list prices. Pharmacy benefit managers also contract with pharmacies to dispense medications purchased by the plan's beneficiaries. Pharmacy benefit managers are compensated by retaining a portion of what—again in theory—should be shared savings on the cost of medications.

- b. *The Manufacturers.* The Manufacturers produce the at-issue insulin medications.<sup>5</sup> Each sets a list price for its products. The term “list price” often is used interchangeably with the Wholesale Acquisition Cost (WAC) (defined by federal law as the undiscounted list price for a drug or biologic to wholesalers or direct purchasers). The manufacturers self-report list prices to publishing compendiums such as First DataBank, Medi-Span, or Redbook, who then publish those prices.<sup>6</sup>

19. Given the PBMs’ purchasing power and their control over formularies that govern the availability of drugs, their involvement should drive list prices down. Instead, to gain access to the PBMs’ formularies, the Manufacturers artificially inflate their list prices and then pay a significant, but undisclosed, portion of the inflated price back to the PBMs (the “Manufacturer Payments”).<sup>7</sup> The Manufacturer Payments bear a variety of

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<sup>5</sup> There are three types of insulin medications. First are *biologics*, which are manufactured insulins derived from living organisms. Second are *biosimilars*, which are “highly similar” copies of biologics. They are similar in concept to “generic” drugs; but in seeking approval they use biologics (rather than drugs) as comparators. Third, the confusingly-named *authorized generics* are not true generics—they are an approved brand-name drug marketed without the brand name on the label. FDA approved the original insulins as drug products rather than biologics, so although there was a regulatory pathway to introduce biosimilars generally (copies of biologics), companies could not introduce insulin biosimilars because their comparators were “drugs” rather than “biologics.” In 2020, FDA moved insulin to the biologic regulatory pathway, thus opening the door to approval of biosimilars through an abbreviated approval process. Also see Appendix A to this Complaint (Glossary).

<sup>6</sup> The related term Average Wholesale Price (AWP) is the published price for a drug sold by wholesalers to retailers.

<sup>7</sup> In this Complaint, “Manufacturer Payments” is defined as all payments or financial benefits of any kind conferred by the Manufacturer Defendants to PBM Defendants (or a subsidiary, affiliated entity, or group purchasing organization or rebate aggregator acting on a PBM’s behalf), either directly via contract or indirectly via Manufacturer-controlled intermediaries. Manufacturer Payments includes rebates, administrative fees, inflation fees, pharmacy supplemental discounts, volume discounts, price or margin guarantees and any other form of consideration exchanged.

dubious labels—rebates, discounts, credits, inflation/price protection fees, administrative fees, etc. By whatever name, the inflated list prices and resulting Manufacturer Payments are a quid pro quo for inclusion and favorable placement on the PBMs’ formularies.<sup>8</sup>

20. Contracts between PBM Defendants and payors like Plaintiff tie the definition of “rebates” to patient drug utilization. But the contracts between PBMs and Manufacturers define “rebates” and other Manufacturer Payments differently, e.g., calling rebates for formulary placement “administrative fees.” Defendants thus profit from the “rebates” and other Manufacturer Payments, and the payments are beyond a payor’s contractual audit right to verify the accuracy of “rebate” payments they receive.

21. The PBMs’ staggering revenues vastly exceed the fair market value of the services they provide. And specifically, the amount of Manufacturer Payments the PBMs receive in connection with the at-issue drugs vastly exceeds the fair market value of the services they provide with respect to those drugs.

22. The Manufacturers’ list prices are not the result of free-market competition for payors’ business. The Manufacturers’ list prices are so untethered from the net prices that the Manufacturers ultimately realize that the Manufacturers know the list price constitutes a false price. It does not reflect the Manufacturers’ actual costs to produce the at-issue drugs or the fair market value of those drugs.<sup>9</sup>

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<sup>8</sup> Favorable or preferred placement may, for example, involve placing a branded product in a lower cost-sharing tier or relaxing utilization controls (such as prior authorization requirements or quantity limits). Favorable placement of a relatively more expensive drug encourages use of that drug and leads to higher out-of-pocket costs for payors and co-payors.

<sup>9</sup> “Net price” refers to the price the manufacturer ultimately realizes, i.e., the list price less rebates, discounts, etc. (net sales divided by volume). At times, Defendants’ representatives use “net price” to refer to the amount payors or plan members pay for medications. In this Complaint, “net price” refers to the former—the amount that the Defendant Manufacturers realize for the at-issue drugs, which is roughly the List Price less Manufacturer Payments.

23. The PBMs grant formulary status based upon the highest inflated price—which the PBMs know is false—and upon which diabetes medications generate the largest profits for themselves.

24. The Insulin Pricing Scheme creates a “best of both worlds” scenario for Defendants. The Manufacturer Defendants buy formulary access and thereby increase their revenues while the PBM Defendants receive significant, undisclosed Manufacturer Payments.

25. The PBM Defendants profit off the Insulin Pricing Scheme in numerous ways, including: (1) retaining a significant, but undisclosed, share of the Manufacturer Payments, either directly or through rebate aggregators, (2) using the price produced by the Insulin Pricing Scheme to generate unwarranted profits from pharmacies, and (3) relying on those same artificial list prices to drive up the PBMs’ margins and pharmacy-related fees, including those relating to their mail-order pharmacies.

26. As detailed below, although the PBM Defendants represent both publicly and to their client payors that they use their market power to drive down prices for diabetes medications, these representations are false and deceptive. Instead, the PBMs intentionally incentivize the Manufacturers to inflate their list prices. The PBMs’ “negotiations” intentionally drive up the price of the at-issue drugs and are directly responsible for the skyrocketing prices of diabetes medications, which confers unearned benefits upon the PBMs and Manufacturers alike.

27. Because the purchase price of every at-issue diabetes medication flows from the false list prices generated by Defendants’ unfair and deceptive scheme, every payor in the United States that purchases these life-sustaining drugs, including Plaintiff, has been directly harmed by the Insulin Pricing Scheme.

28. Even if temporary reductions in Plaintiff's costs for the at-issue drugs occurred from time to time, those costs remained higher than those that would have resulted from a transparent exchange in a free and open market.

29. As a payor for and purchaser of the at-issue drugs, Plaintiff has been overcharged substantial amounts of money during the relevant period as a direct result of the Insulin Pricing Scheme.

30. This action alleges that Defendants violated the Racketeer Influenced and Corrupt Organizations Act and Ohio statutory and common law by engaging in the Insulin Pricing Scheme. The Insulin Pricing Scheme directly and foreseeably harmed, and continues to harm, Plaintiff.

31. This action seeks injunctive relief, restitution, disgorgement, actual damages, punitive damages, attorneys' fees and costs, and all other available relief to address and abate the harm caused by the Insulin Pricing Scheme.

32. The "relevant period" alleged in this action is from 2008 through the present.

## **II. PARTIES**

### **A. Plaintiff**

33. **Plaintiff The City of Cleveland, Ohio**, ("Cleveland") is a municipal corporation organized and chartered pursuant to Article XVIII, Section 7 of the Ohio Constitution. Plaintiff has all the powers of local self-government and all other powers possible for a city to have under the constitution and the laws of the State of Ohio, which are exercised in the manner prescribed by the Charter of the City of Cleveland. .

34. Plaintiff, as a government entity, provides vital services including public safety, emergency management, and health services to more than 372,632 residents.

35. Any increase in spending has a detrimental effect on Plaintiff's overall budget and, in turn, negatively impacts its ability to provide necessary services to the community.

36. The Insulin Pricing Scheme has had such an effect.

37. Additionally, as a government employer, Plaintiff provides health benefits to its employees, retirees, and their dependents ("Beneficiaries"). One of the benefits Plaintiff offers its Beneficiaries is paying a substantial share of the purchase price of their pharmaceutical drugs, including the at-issue diabetes medications.

38. Plaintiff maintains self-insured health plans for its Beneficiaries. In recent years, Cleveland's Plan has covered approximately 16,000 members per year (many of whom carried coverage for immediate family).

39. In 2017 and 2019, Plaintiff's most significant prescription expense by therapeutic class was for antidiabetic drugs, with more than \$2,000,000 being spent by Plaintiff on this class of drugs in each of those years alone. Over the course of the relevant period—as prices continued to rise—Plaintiff spent significant amounts of public monies in overcharges to the detriment of its Beneficiaries and the public.

40. Plaintiff seeks relief for the harm suffered by Defendants' misrepresentations and omissions regarding their illegal Insulin Pricing Scheme.

#### **B. Manufacturer Defendants**

41. **Defendant Eli Lilly and Company** ("Eli Lilly") is an Indiana corporation with its principal place of business at Lilly Corporate Center, Indianapolis, Indiana 46285. It is a citizen of the State of Indiana.

42. Eli Lilly is and has since 1962 been registered to do business in the State of Ohio. Eli Lilly may be served through its registered agent: National Registered Agents, Inc., 4400 Easton Commons Way, Suite 125, Columbus, Ohio 43219.

43. In Ohio and nationally, Eli Lilly manufactures, promotes, and distributes several at-issue diabetes medications: Humulin N (first U.S. approval in 1982), Humulin R (first U.S. approval in 1982), Humalog (first U.S. approval in 1996), Trulicity (first U.S. approval in 2014), and Basaglar (first U.S. approval in 2015).

44. Eli Lilly's domestic revenues from 2019 to 2021 were \$11.9 billion from Trulicity, \$4.48 billion from Humalog, \$2.58 billion from Humulin, and \$2.31 billion from Basaglar.<sup>10</sup>

45. Eli Lilly's global revenues in 2018 were \$3.2 billion from Trulicity, \$2.99 billion from Humalog, \$1.33 billion from Humulin, and \$801 million from Basaglar.<sup>11</sup>

46. Eli Lilly transacts business in Ohio, including in Cleveland, targeting these markets for its products, including the at-issue diabetes medications.

47. Eli Lilly employs sales representatives throughout Ohio to promote and sell Humulin N, Humulin R, Humalog, Trulicity, and Basaglar, and it utilizes wholesalers (McKesson, AmeriSource Bergen, and Cardinal Health) to distribute the at-issue products to pharmacies and healthcare professionals within Ohio, including in Cleveland.

48. Eli Lilly also directs advertising and informational materials to Ohio and Cleveland physicians and potential users of Eli Lilly's products.

49. At all relevant times, in furtherance of the Insulin Pricing Scheme, Eli Lilly published its prices for the at-issue diabetes medications throughout Ohio with the express knowledge that payment and reimbursement by Plaintiff would be based on those false list prices.

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<sup>10</sup> Eli Lilly Annual Report (Form 10-K) (FYE Dec. 31, 2021).

<sup>11</sup> Eli Lilly Annual Report (Form 10-K) (FYE Dec. 31, 2018).



50. During the relevant period, Plaintiff purchased Eli Lilly's at-issue drugs at prices based on false list prices generated by the Insulin Pricing Scheme through its employee health plans.

51. All of the Eli Lilly diabetes medications related to the at-issue transactions were paid for and/or reimbursed in Ohio based on the specific false and inflated prices Eli Lilly caused to be published in Ohio in furtherance of the Insulin Pricing Scheme.

52. **Defendant Sanofi-Aventis U.S. LLC ("Sanofi")** is a Delaware limited liability company with its principal place of business at 55 Corporate Drive, Bridgewater, New Jersey 08807. It is a citizen of the State of Delaware and the State of New Jersey.

53. Sanofi may be served through its registered agent: Corporation Service Company, 251 Little Falls Drive, Wilmington, Delaware 19808.

54. Sanofi manufactures, promotes, and distributes pharmaceutical drugs both in Ohio and nationally, including several at-issue diabetes medications: Lantus (first U.S. approval in 2000), Apidra (first U.S. approval in April 2004), Toujeo (first U.S. marketing authorization in February 2015), and Soliqua (first U.S. approval in November 2016).

55. Sanofi considers Lantus one of its "flagship products" and "one of Sanofi's leading products in 2021 with net sales of €2,494 million" (\$2.95 billion) net sales of €2,661million (\$3.04 billion) in 2020, representing 7.4% of the company's net sales for 2020.<sup>12</sup>

56. Sanofi's U.S. net sales in 2019 were \$1.29 billion from Lantus, \$323.7 million from Toujeo, and \$51.5 million from Apidra.<sup>13</sup>

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<sup>12</sup> Sanofi Annual Report (Form 20-F) (FYE Dec. 31, 2021); Sanofi Annual Report (Form 20-F) (FYE Dec. 31, 2020).

<sup>13</sup> Sanofi Annual Report (Form 20-F) (FYE Dec. 31, 2019).

57. Sanofi transacts business in Ohio, including in Cleveland, targeting these markets for its products, including the at-issue diabetes medications.

58. Sanofi employs sales representatives throughout Ohio and in this District to promote and sell Lantus, Toujeo, Apidra, and Soliqua, and it utilizes wholesalers to distribute the at-issue products to pharmacies and healthcare professionals within Ohio, including in Cleveland.

59. Sanofi also directs advertising and informational materials to Ohio physicians and potential users of Sanofi's products for the specific purpose of selling the at-issue drugs in Ohio, including Cleveland, and profiting from the Insulin Pricing Scheme.

60. At all relevant times, in furtherance of the Insulin Pricing Scheme, Sanofi published its prices of its at-issue diabetes medications throughout Ohio for the purpose of payment and reimbursement by payors, including Plaintiff.

61. During the relevant period, Plaintiff purchased Sanofi's at-issue drugs at prices based on false list prices generated by the Insulin Pricing Scheme through its employee health plans.

62. All of the Sanofi diabetes medications related to the at-issue transactions were paid for and/or reimbursed in Ohio and Cleveland based on the specific false and inflated prices Sanofi caused to be published in Ohio in furtherance of the Insulin Pricing Scheme.

63. **Defendant Novo Nordisk Inc.** ("Novo Nordisk") is a Delaware corporation with its principal place of business at 800 Scudders Mill Road, Plainsboro, New Jersey 08536. It is a citizen of the State of Delaware and the State of New Jersey.

64. Novo Nordisk may be served through its registered agent: The Corporation Trust Company, 1209 Orange Street, Wilmington, Delaware 19801.

65. Novo Nordisk manufactures, promotes, and distributes pharmaceutical drugs both in Ohio and nationally, including at-issue diabetic medications: Novolin R (first U.S. approval in 1991), Novolin N (first U.S. approval in 1991), Novolog (first U.S. approval in June 2002), Levemir (first U.S. approval in June 2005), Victoza (first U.S. approval in January 2010), Tresiba (first U.S. approval in 2015), and Ozempic (first U.S. approval in 2017).

66. Nordisk's combined net sales of these drugs in the U.S. from 2018 to 2020 totaled approximately \$18.1 billion (\$6.11 billion for Victoza alone).<sup>14</sup>

67. Novo Nordisk's global revenues for "total diabetes care" over that three-year period exceeded \$41 billion.<sup>15</sup>

68. Novo Nordisk transacts business in Ohio and in Cleveland, targeting these markets for its products, including the at-issue diabetes medications.

69. Novo Nordisk employs sales representatives throughout Ohio and Cleveland to promote and sell Novolin R, Novolin N, Novolog, Levemir, Tresiba, Victoza, and Ozempic, and it utilizes wholesalers to distribute the at-issue products to pharmacies and healthcare professionals within Ohio, including in Cleveland.

70. Novo Nordisk also directs advertising and informational materials to Ohio and Cleveland physicians and potential users of Novo Nordisk's products.

71. At all relevant times, in furtherance of the Insulin Pricing Scheme, Novo Nordisk published its prices of its at-issue diabetes medications throughout Ohio for the purpose of payment and reimbursement by Plaintiff.

72. During the relevant period, Plaintiff purchased Novo Nordisk's at-issue

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<sup>14</sup> Novo Nordisk Annual Report (Form 20-F & Form 6-K) (FYE Dec. 31, 2020).

<sup>15</sup> *Id.*

diabetes medications at prices based on false list prices generated by the Insulin Pricing Scheme through its employee health plans.

73. All Novo Nordisk diabetes medications related to the at-issue transactions were paid for and/or reimbursed in Ohio based on the specific false and inflated prices Novo Nordisk caused to be published in Ohio in furtherance of the Insulin Pricing Scheme.

74. As set forth above, Defendants Eli Lilly, Novo Nordisk, and Sanofi are referred to collectively as the “Manufacturer Defendants” or the “Manufacturers.”

### **C. PBM Defendants**

75. **Defendant CVS Health Corporation (“CVS Health”)** is a Delaware corporation with its principal place of business at One CVS Drive, Woonsocket, Rhode Island 02895. It is a citizen of the State of Delaware and the State of Rhode Island.

76. CVS Health transacts business and has locations throughout the United States and Ohio.

77. CVS Health may be served through its registered agent: The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

78. CVS Health—through its executives and employees, including its CEO, Chief Medical Officer, Executive Vice Presidents, Senior Executives in Trade Finance, Senior Vice Presidents, and Chief Communication Officers—is directly involved in creating and implementing company policies that inform its PBM services and formulary construction, including with respect to the at-issue drugs involved in the Insulin Pricing Scheme.

79. CVS Health’s conduct had a direct effect in Ohio and damaged Plaintiff as a payor and purchaser.

80. On a regular basis, CVS Health executives and employees communicate with and direct its subsidiaries related to the at-issue PBM services and formulary activities.

81. In each annual report for at least the last decade, CVS Health (or its predecessor) has repeatedly and explicitly stated that CVS Health:

- designs pharmacy benefit plans that minimize the costs to the client while prioritizing the welfare and safety of the clients' members;
- negotiates with pharmaceutical companies to obtain discounted acquisition costs for many of the products on CVS Health's drug lists, and these negotiated discounts enable CVS Health to offer reduced costs to clients; and
- utilizes an independent panel of doctors, pharmacists, and other medical experts, referred to as its Pharmacy and Therapeutics Committee, to select drugs that meet the highest standards of safety and efficacy for inclusion on its drug lists.<sup>16</sup>

82. CVS Health publicly represents that CVS Health lowers the cost of the at-issue drugs. For example, in 2016 CVS Health announced a new program to "reduce overall spending in diabetes" that is available in all states, including Ohio, stating:

*CVS Health* introduced a new program available to help the company's pharmacy benefit management (PBM) clients to improve the health outcomes of their members, *lower pharmacy costs [for diabetes medications]* through aggressive trend management and decrease medical costs . . . [and that] participating clients could save between \$3000 to \$5000 per year for each member who successfully improves control of their diabetes." (emphasis added)

83. A 2017 CVS Health press release stated that "*CVS Health* pharmacy benefit management (PBM) strategies reduced trend for commercial clients to 1.9 percent per member per year the lowest in five years. Despite manufacturer price increases of near 10 percent, CVS Health kept drug price growth at a minimal 0.2 percent."

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<sup>16</sup> CVS Health Annual Report (Form 10-K) (FYE Dec. 31, 2009-2019).

84. In November 2018, CVS Health acquired Aetna for \$69 billion and became the first combination of a major health insurer, PBM, and mail-order and retail pharmacy chain. CVS Health thus controls the health plan/insurer, the PBM, and the pharmacies utilized by approximately 40 million Aetna members in the United States, including Ohio. CVS Health controls the entire drug pricing chain for these 40 million Americans.

85. CVS Health is the immediate or indirect parent of many pharmacy subsidiaries that own and operate hundreds of pharmacies throughout Ohio—including CVS Pharmacy, Inc., which is registered to do business in the state—that dispensed and received payment for the at-issue diabetes medications throughout the relevant period. According to a CVS Health press release, it “maintains a national network of approximately 66,000 retail pharmacies, consisting of approximately 40,000 chain pharmacies (including CVS Pharmacy locations) and approximately 26,000 independent pharmacies, in the United States.”

86. **Defendant CVS Pharmacy, Inc. (“CVS Pharmacy”)** is a Rhode Island corporation whose principal place of business is at the same location as CVS Health. It is a citizen of the State of Rhode Island.

87. CVS Pharmacy—a wholly owned subsidiary of CVS Health—is and has since 1996 been registered to do business in the State of Ohio. It may be served through its registered agent CT Corporation System, 4400 Easton Commons Way, Suite 125, Columbus, Ohio 43219.

88. CVS Pharmacy is the immediate or indirect parent of many pharmacy subsidiaries that own and operate hundreds of pharmacies throughout Ohio and is directly involved in these pharmacies’ dispensing and payment policies related to the at-issue diabetes medications.

89. CVS Pharmacy is also the immediate and direct parent of Defendant Caremark Rx, LLC.

90. CVS Pharmacy holds numerous pharmacy licenses in Cleveland and throughout the State of Ohio.

91. During the relevant period, CVS Pharmacy provided retail pharmacy services in Ohio that gave rise to and implemented the Insulin Pricing Scheme, which damaged payors, including Plaintiff.

92. **Defendant Caremark Rx, LLC** is a Delaware limited liability company and an immediate or indirect parent of many subsidiaries, including pharmacy benefit management and mail-order subsidiaries that engaged in the activities in Ohio that gave rise to this action.

93. Caremark Rx, LLC is a subsidiary of Defendant CVS Pharmacy, which is a wholly owned subsidiary of Defendant CVS Health and its principal place of business is at the same location as CVS Pharmacy and CVS Health. It is a citizen of the State of Delaware and the State of Rhode Island.

94. Caremark Rx, LLC may be served through its registered agent: The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

95. During the relevant period, Caremark Rx, LLC provided PBM and mail-order pharmacy services in Ohio that gave rise to and implemented the Insulin Pricing Scheme and damaged payors in Ohio, including Plaintiff.

96. **Defendant Caremark LLC** is a California limited liability company whose principal place of business is at the same location as CVS Health. It is a citizen of the State of California and the State of Rhode Island.

97. Caremark, LLC is a subsidiary of Caremark Rx, LLC, which is a subsidiary of Defendant CVS Pharmacy, which is a wholly owned subsidiary of Defendant CVS Health.

98. Caremark, LLC is and has since 1979 been registered to do business in Ohio. Caremark, LLC may be served through its registered agent: CT Corporation System, 4400 Easton Commons Way, Suite 125, Columbus, Ohio 43219.

99. Caremark, LLC holds numerous pharmacy and wholesaler licenses in Ohio.

100. During the relevant period, Caremark, LLC provided PBM and mail-order pharmacy services in Ohio and in Cleveland that gave rise to and implemented the Insulin Pricing Scheme, which damaged payors, including Plaintiff.

101. **Defendant CaremarkPCS Health, LLC (“CaremarkPCS Health”)** is a Delaware limited liability company whose principal place of business is at the same location as CVS Health. It is a citizen of the State of Delaware and the State of Rhode Island.

102. CaremarkPCS Health is a subsidiary of CaremarkPCS, LLC, which is a subsidiary of Caremark Rx, LLC, which is a subsidiary of Defendant CVS Pharmacy, which is a wholly owned subsidiary of Defendant CVS Health.

103. CaremarkPCS Health is and has since 2000 been registered to do business in Ohio. CaremarkPCS Health may be served through its registered agent: CT Corporation System, 4400 Easton Commons Way, Suite 125, Columbus, Ohio 43219.

104. CaremarkPCS Health, doing business as CVS Caremark, provides pharmacy benefit management services.

105. During the relevant period, CaremarkPCS Health provided PBM services in the State of Ohio, which gave rise to and implemented the Insulin Pricing Scheme, which damaged payors, including Plaintiff.



106. During the relevant period, CaremarkPCS Health was directly involved in PBM and mail-order pharmacy services that gave rise to and implemented the Insulin Pricing Scheme, which damaged payors, including Plaintiff.

107. Indeed, CaremarkPCS Health provided pharmacy benefit services to Plaintiff from at least 2013 through the current day based on Plaintiff's reliance upon CaremarkPCS Health's response to the County's request for proposals and upon other representations made in the formation and maintenance of the relationship.

108. Defendants CaremarkPCS Health and Caremark, LLC are agents and/or alter egos of Caremark Rx, LLC, CVS Pharmacy, and CVS Health.

109. As a result of numerous interlocking directorships and shared executives, Caremark Rx, LLC, CVS Pharmacy, and CVS Health are directly involved in the conduct of and control CaremarkPCS Health and Caremark, LLC's operations, management, and business decisions related to the at-issue formulary construction, Manufacturer Payments, and mail-order and retail pharmacy services to the ultimate detriment of Plaintiff. For example:

- a. During the relevant period, these parent and subsidiaries have had common officers and directors, including:
  - Thomas S. Moffatt, Vice President and Secretary of Caremark Rx, LLC, CaremarkPCS Health, and Caremark, LLC, also served as Vice President, Assistant Secretary, and Senior Legal Counsel at CVS Health and as Vice President, Secretary and Senior Legal Counsel of CVS Pharmacy;
  - Melanie K. Luker, Assistant Secretary of Caremark Rx, LLC, CaremarkPCS Health, and Caremark, LLC, also served as Manager of Corporate Services at CVS Health;
  - Carol A. Denale, Senior Vice President and Treasurer of Caremark Rx, LLC, also served as Senior Vice President, Treasurer, and Chief Risk Officer at CVS Health;

- John M. Conroy was VP of Finance at CVS Health in 2011 and President and Treasurer of Caremark, LLC and CaremarkPCS Health in 2019;
  - Sheelagh Beaulieu served as Senior Director of Income Tax at CVS Health while also acting as the Assistant Treasurer at CaremarkPCS Health and Caremark, LLC.
- b. CVS Health owns all the stock of CVS Pharmacy, which owns all the stock of Caremark Rx, LLC, which owns all the stock of Caremark LLC. CVS Health directly or indirectly owns CaremarkPCS Health in its entirety.
- c. CVS Health, as a corporate family, does not operate as separate entities. Its public filings, documents, and statements present its subsidiaries—including CVS Pharmacy, Caremark Rx, LLC, Caremark, LLC, and CaremarkPCS Health as divisions or departments of one unified “diversified health services company” that “works together across our disciplines” to “create unmatched human connections to transform the health care experience.” The day-to-day operations of this corporate family reflect these public statements. These entities are a single business enterprise and should be treated as such as to all legal obligations discussed in this Complaint.<sup>17</sup>
- d. All executives of CaremarkPCS Health, Caremark, LLC, Caremark Rx, LLC, and CVS Pharmacy ultimately report to the executives at CVS Health, including its President and CEO.
- e. CVS Health’s CEO, Chief Medical Officer, Executive Vice Presidents, Senior Executives in Trade Finance, Senior Vice Presidents, and Chief Communication

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<sup>17</sup> CVS Health Annual Report (Form 10-K) (FY 2009-2019); CVS Health, *Our Purpose*, <https://cvshealth.com/about-cvs-health/our-purpose> (last visited Sept. 9, 2022); CVS Health, *Quality of Care*, <https://cvshealth.com/health-with-heart/improving-health-care/quality-of-care> (last visited Sept. 9, 2022).

Officers are directly involved in the policies and business decisions by Caremark, LLC and CaremarkPCS Health that give rise to Plaintiff's claims.

110. Collectively, Defendants CVS Health, CVS Pharmacy, Caremark Rx, LLC, Caremark, LLC, and CaremarkPCS Health, including all predecessor and successor entities, are referred to as "CVS Caremark."

111. CVS Caremark is named as a Defendant in its capacities as a PBM and as a mail-order pharmacy.

112. In its capacity as a PBM, CVS Caremark coordinated with Novo Nordisk, Eli Lilly, and Sanofi regarding the price of the at-issue diabetes medications, as well as for the placement of these firms' diabetes medications on CVS Caremark's formularies.

113. CVS Caremark has the largest PBM market share based on total prescription claims managed. Its pharmacy services segment provides, among other things, plan design offerings and administration, formulary management, retail pharmacy network management services, mail-order pharmacy, specialty pharmacy and infusion services, clinical services, and medical spend management." In 2021, CVS Caremark's pharmacy services segment "surpassed expectations" and had a "record selling season of nearly \$9 billion in net new business wins for 2022." In all, it generated just over \$153 billion in total revenues (on top of total 2019-2020 segment revenues exceeding \$283 billion).<sup>18</sup>

114. At all relevant times, CVS Caremark offered pharmacy benefit services nationwide and to Ohio payors, including Plaintiff, and derived substantial revenue therefrom. In doing so, it made misrepresentations while concealing the Insulin Pricing Scheme and utilized the false prices generated by the Insulin Pricing Scheme.

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<sup>18</sup> CVS Health Annual Report (Form 10-K) (FYE Dec. 31, 2021).

115. At all relevant times, CVS Caremark offered PBM services nationwide and maintained standard formularies that were used nationwide, including in Ohio, and by Plaintiff. Those formularies included the diabetes medications at issue here, and CVS Caremark participated in pricing these drugs based off the list prices it knew to be false.

116. During the relevant period, CVS Caremark provided PBM services directly to Plaintiff and, in doing so, set the prices that Plaintiff paid for the at-issue drugs based on the false list prices generated by the Insulin Pricing Scheme. Plaintiff paid CVS Caremark for the at-issue drugs.

117. During the relevant period, CVS Caremark dispensed the at-issue medications nationwide and directly to Plaintiff and its Beneficiaries through its mail-order pharmacies. CVS Caremark derived substantial revenue from these activities in Ohio.

118. In short, CVS Caremark not only played a critical role in the overall Insulin Pricing Scheme, but its direct contact with Plaintiff caused Plaintiff harm.

119. In requesting proposals for pharmacy benefit manager services for its self-insured prescription drugs program on behalf of its Beneficiaries, Plaintiff specified that it was seeking to obtain “cost effective solutions for employees and the City” as it related to prescription drug benefits.

120. CVS Caremark purchased drugs directly from manufacturers for dispensing through its pharmacy network.

121. During the relevant period, CVS Caremark made representations to Plaintiff through proposals to provide PBM services in response to Plaintiff’s requests for proposals and, in doing so, CVS Caremark reinforced the false list prices for the at-issue drugs generated by the Insulin Pricing Scheme.

122. In its capacity as a retail pharmacy, CVS Caremark further and knowingly profited from the false list prices produced by the Insulin Pricing Scheme by pocketing the spread between acquisition cost for the at-issue drugs (an amount well below the list price generated by the Insulin Pricing Scheme), and the amounts it received from payors (which amounts were based on the false list prices and, in many cases, were set by CVS Caremark in its capacity as a PBM).

123. During the relevant period, CVS Caremark provided mail-order and retail pharmacy services nationwide and within the State of Ohio and employed prices based on the false list prices generated by the Insulin Pricing Scheme.

124. At all relevant times, CVS Caremark dispensed the at-issue medications nationwide and within the State of Ohio through its mail-order and retail pharmacies and it derived substantial revenue from these activities in Ohio.

125. At all relevant times, CVS Caremark had express agreements with Defendants Novo Nordisk, Sanofi, and Eli Lilly related to the Manufacturer Payments paid by the Manufacturer Defendants to CVS Caremark, as well as agreements related to the Manufacturers' at-issue drugs sold through CVS Caremark's mail-order pharmacies.

126. **Defendant Evernorth Health, Inc. ("Evernorth")**, formerly known as Express Scripts Holding Company, is a Delaware corporation with its principal place of business at One Express Way, St. Louis, Missouri 63121.<sup>19</sup> It is a citizen of the State of Delaware and the State of Missouri.

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<sup>19</sup> Until 2021, Evernorth Health, Inc. operated under the name Express Scripts Holding Company. In this Complaint "Evernorth" refers to Evernorth Health, Inc. and Express Scripts Holding Company.

127. Evernorth is and has been since 2012 registered to do business in the State of Ohio. Evernorth may be served through its registered agent: CT Corporation System, 4400 Easton Commons Way, Suite 125, Columbus, Ohio 43219.

128. Evernorth, through its executives and employees, including its CEO and Vice Presidents, is directly involved in shaping the company policies that inform its PBM services and formulary construction, including with respect to the at-issue drugs, related to the Insulin Pricing Scheme.

129. Evernorth's conduct had a direct effect in Ohio and upon Plaintiff.

130. Evernorth executives and employees regularly communicate with and direct its subsidiaries related to the at-issue PBM services and formulary activities.

131. Evernorth is the immediate or indirect parent of pharmacy and PBM subsidiaries operating in Ohio, who engaged in the activities that gave rise to this action.<sup>20</sup>

132. In 2018, Evernorth merged with Cigna in a \$67 billion deal to consolidate their businesses as a major health insurer, PBM, and mail-order pharmacy. The Evernorth corporate family thus controls the health plan/insurer, the PBM, and the mail-order pharmacies utilized by approximately 15 million Cigna members in the United States, including Ohio. Evernorth controls the drug pricing chain for these 15 million Americans.

133. Evernorth's annual reports over the past several years have repeatedly and explicitly:<sup>21</sup>

- Acknowledged it is directly involved in the company's PBM services, describing itself as "the largest stand-alone PBM company in the United States."

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<sup>20</sup> Express Scripts Annual Report (Form 10-K, Exhibit 21) (FYE Dec. 31, 2018).

<sup>21</sup> Express Scripts Annual Reports (FY 2009-2019); Cigna Annual Report (Form 10-K) FYE 2020 & 2021).

- Stated that Evernorth controls costs, including for example, that it: “provid[es] products and solutions that focus on improving patient outcomes and assist in controlling costs; evaluat[es] drugs for efficacy, value and price to assist clients in selecting a cost-effective formulary; [and] offer[s] cost-effective home delivery pharmacy and specialty services that result in cost savings for plan sponsors and better care for members.”

134. Even after the merger with Cigna, Evernorth “operates various group purchasing organizations that negotiate pricing for the purchase of pharmaceuticals and formulary rebates with pharmaceutical manufacturers on behalf of their participants” and operates the company’s Pharmacy Rebate Program while its subsidiary Express Scripts provides “formulary management services” that ostensibly “assist customers and physicians in choosing clinically-appropriate, cost-effective drugs and prioritize access, safety and affordability.” In 2021, Evernorth reported adjusted revenues of \$131.9 billion (representing 75.8% of Cigna Corporation’s revenues), which was up from \$116.1 billion in 2020.<sup>22</sup>

135. **Defendant Express Scripts, Inc.** is a Delaware corporation and is a wholly owned subsidiary of Defendant Evernorth. Express Scripts, Inc.’s principal place of business is at the same location as Evernorth. It is a citizen of the State of Delaware and the State of Missouri.

136. Express Scripts, Inc. is and has since 2009 been registered to do business in Ohio and may be served through its registered agent: CT Corporation System, 4400 Easton Commons Way, Suite 125, Columbus, Ohio 43219.

137. Express Scripts, Inc. holds one or more pharmacy licenses in Ohio.

138. Express Scripts, Inc. is the immediate or indirect parent of pharmacy and

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<sup>22</sup> Cigna Annual Report (Form 10-K) (FYE Dec. 31, 2021).

PBM subsidiaries that operate throughout Ohio that engaged in the conduct, which gave rise to this action.<sup>23</sup>

139. **Defendant Express Scripts Administrators, LLC**, doing business as Express Scripts and formerly known as Medco Health, LLC, is a Delaware limited liability company and is a wholly owned subsidiary of Evernorth. Its principal place of business is at 100 Parsons Pond Drive, Franklin Lakes, New Jersey 07417. It is a citizen of the State of Delaware and the State of New Jersey.

140. Express Scripts Administrators, LLC is and has been since 2004 registered to do business in Ohio and may be served through its registered agent: CT Corporation System, 4400 Easton Commons Way, Suite 125, Columbus, Ohio 43219.

141. During the relevant period, Express Scripts Administrators, LLC provided the PBM services in Ohio that gave rise to and implemented the Insulin Pricing Scheme that damaged payors, including Plaintiff.

142. **Defendant Medco Health Solutions, Inc. (“Medco”)** is a Delaware Corporation whose principal place of business is at the same location as Evernorth. It is a citizen of the State of Delaware and the State of Missouri.

143. Medco has since 2002 been registered to do business in Ohio. Medco may be served through its registered agent: CT Corporation System, 4400 Easton Commons Way, Suite 125, Columbus, Ohio 43219.

144. In 2012, Express Scripts acquired Medco for \$29 billion.

145. Prior to the merger, Express Scripts and Medco were two of the largest PBMs in the United States and in Ohio.

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<sup>23</sup> Express Scripts Annual Report (Form 10-K, Exhibit 21) (FYE Dec. 31, 2018).



146. Prior to the merger, Medco provided the at-issue PBM and mail-order services in Ohio, which gave rise to and implemented the Insulin Pricing Scheme, which damaged payors, including Plaintiff.

147. Following the merger, all of Medco's PBM and mail-order pharmacy functions were combined into Express Scripts. The combined company (Medco and Express Scripts) continued under the name Express Scripts with all of Medco's payor customers becoming Express Scripts' customers—including Plaintiff. The combined company covered over 155 million lives at the time of the merger.

148. At the time of the merger, on December 6, 2011, in his testimony before the Senate Judiciary Committee, then-CEO of Medco David Snow publicly represented that “the merger of Medco and Express Scripts will result in immediate savings to our clients and, ultimately, to consumers. This is because our combined entity will achieve even greater purchasing volume discounts [Manufacturer Payments] from drug manufacturers and other suppliers.”<sup>24</sup>

149. At the same time, the then-CEO of Express Scripts, George Paz, provided written testimony to the Senate Judiciary Committee's Subcommittee on Antitrust, Competition Policy and Consumer Rights, stating: “A combined Express Scripts and Medco will be well-positioned to protect American families from the rising cost of prescription medicines.” First on Mr. Paz's list of “benefits of this merger” was “[g]enerating greater cost savings for patients and plan sponsors.”<sup>25</sup>

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<sup>24</sup> Transcript available at <https://www.judiciary.senate.gov/imo/media/doc/11-12-6SnowTestimony.pdf> (last visited Jan. 13, 2023).

<sup>25</sup> Transcript available at <https://www.judiciary.senate.gov/imo/media/doc/11-12-6PazTestimony.pdf> (last visited Jan. 13, 2023).

150. **Defendant ESI Mail Pharmacy Service, Inc.** is a Delaware corporation and is a wholly owned subsidiary of Defendant Evernorth. ESI Mail Pharmacy Service, Inc.'s principal place of business is at the same location as Evernorth. It is a citizen of the State of Delaware and the State of Missouri.

151. ESI Mail Pharmacy Service, Inc. may be served through its registered agent: CT Corporation System, 120 S. Central Ave., Clayton, MO 63105.

152. ESI Mail Pharmacy Service, Inc. holds several pharmacy licenses in Ohio.

153. **Defendant Express Scripts Pharmacy, Inc.** is a Delaware corporation and is a wholly owned subsidiary of Defendant Evernorth. Express Scripts Pharmacy, Inc.'s principal place of business is at the same location as Evernorth. It is a citizen of the State of Delaware and the State of Missouri.

154. Express Scripts Pharmacy, Inc. is and has been since 2013 registered to do business in the State of Ohio. Express Scripts Pharmacy, Inc. may be served through its registered agent: CT Corporation System, 4400 Easton Commons Way, Suite 125, Columbus, Ohio 43219.

155. Express Scripts Pharmacy, Inc. holds one or more wholesaler licenses and holds several pharmacy licenses in Ohio.

156. During the relevant period, Express Scripts Pharmacy, Inc. provided the mail-order pharmacy services in Ohio that gave rise to and implemented the Insulin Pricing Scheme, which damaged payors.

157. As a result of numerous interlocking directorships and shared executives, Evernorth (fka Express Scripts Holding Company, Inc.) and Express Scripts, Inc. control Express Scripts Administrators, LLC, ESI Mail Pharmacy Service, Inc., Medco Health Solutions, Inc., and Express Scripts Pharmacy, Inc.'s operations, management, and

business decisions related to the at-issue formulary construction, negotiations, and mail-order pharmacy services to the ultimate detriment of Plaintiff. For example:

- a. During the relevant period, these parent and subsidiaries have had common officers and directors:
  - Officers and/or directors shared between Express Scripts, Inc. and Evernorth include Bradley Phillips, Chief Financial Officer; David Queller, President; Jill Stadelman, Managing Counsel; Dave Anderson, VP of Strategy; Matt Perlberg, President of Pharmacy Businesses; Bill Spehr, SVP of Sales; and Scott Lambert, Treasury Manager Director;
  - Executives shared between Express Scripts Administrators, LLC and Evernorth include Bradley Phillips, Chief Financial Officer; and Priscilla Duncan, Associate Senior Counsel;
  - Officers and/or directors shared between ESI Mail Pharmacy Service, Inc. and Evernorth include Bradley Phillips, CFO; Priscilla Duncan, Associate Senior Counsel; and Joanne Hart, Treasury Director; and
  - Officers and/or directors shared between Express Scripts Pharmacy, Inc. and Evernorth include Bradley Phillips; Jill Stadelman, Managing Counsel; Scott Lambert, Treasury Manager Director; and Joanne Hart.
- b. Evernorth directly or indirectly owns all the stock of Express Scripts Administrators, LLC, Medco Health Solutions, Inc., ESI Mail Pharmacy Service, Inc., Express Scripts Pharmacy, Inc., and Express Scripts, Inc.<sup>26</sup>
- c. The Evernorth corporate family does not operate as separate entities. Evernorth's public filings, documents, and statements present its subsidiaries, including Express Scripts Administrators, LLC, ESI Mail Pharmacy Service, Inc., Express Scripts Pharmacy, Inc., and Express Scripts, Inc. as divisions or departments of a single company that "unites businesses that have as many as 30+ years of experience . . . [to] tak[e] health services further with integrated

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<sup>26</sup> Express Scripts Annual Report (Form 10-K, Exhibit 21) (FYE Dec. 31, 2018).

data and analytics that help us deliver better care to more people.” The day-to-day operations of this corporate family reflect these public statements. All of these entities are a single business enterprise and should be treated as such as to all legal obligations detailed in this Complaint.<sup>27</sup>

- d. All executives of Express Scripts Administrators, LLC, ESI Mail Pharmacy Service, Inc., Express Scripts Pharmacy, Inc., and Express Scripts, Inc. ultimately report to the executives, including the CEO, of Evernorth.
- e. As stated above, Evernorth’s CEO and other executives and officers are directly involved in the policies and business decisions of Express Scripts Administrators, LLC, ESI Mail Pharmacy Service, Inc., Medco Health Solutions, Inc., Express Scripts Pharmacy, Inc., and Express Scripts, Inc. that gave rise to Plaintiff’s claims in this Complaint.

158. Collectively, Defendants Evernorth Health, Inc., Express Scripts, Inc., Express Scripts Administrators, LLC, ESI Mail Pharmacy Service, Inc., Medco Health Solutions, Inc., and Express Scripts Pharmacy, Inc., including all predecessor and successor entities, are referred to as “Express Scripts.”

159. Express Scripts is named as a Defendant in its capacities as a PBM and mail-order pharmacy.

160. In its capacity as a PBM, Express Scripts coordinates with Novo Nordisk, Eli Lilly, and Sanofi regarding the price of the at-issue diabetes medications, as well as for the placement of these firms’ diabetes medications on Express Scripts’ formularies.

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<sup>27</sup> Express Scripts Annual Reports; Evernorth, <https://www.evernorth.com/> (last visited Sept. 9, 2022).

161. Prior to merging with Cigna in 2019, Express Scripts was the largest independent PBM in the United States.<sup>28</sup> During the relevant period of this Complaint, Express Scripts controlled 30% of the PBM market in the United States. Express Scripts has only grown larger since the Cigna merger.

162. In 2017, annual revenue for Express Scripts was over \$100 billion.<sup>29</sup>

163. As of December 31, 2018, more than 68,000 retail pharmacies, representing over 98% of all retail pharmacies in the nation, participated in Express Scripts' networks.

164. Express Scripts transacts business throughout the United States and Ohio.

165. At all relevant times, Express Scripts derived substantial revenue from providing retail and mail-order pharmacy benefits in Ohio using prices based on the false list prices for the at-issue drugs.

166. At all relevant times, and contrary to its express representations, Express Scripts knowingly insisted that its payor clients use the false list prices produced by the Insulin Pricing Scheme as the basis for reimbursement of the at-issue drugs.

167. At all relevant times, Express Scripts concealed its critical role in the generation of those false list prices.

168. Express Scripts maintained standard formularies that are used nationwide, including in the State of Ohio. During the relevant period, those formularies included drugs produced by the Manufacturer Defendants, including the at-issue medications.

169. In its capacity as a mail-order pharmacy, Express Scripts received payments from Ohio payors for, and set the out-of-pocket price paid for, the at-issue drugs based on the falsely inflated prices produced by the Insulin Pricing Scheme.

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<sup>28</sup> Express Scripts Annual Report (Form 10-K) (FYE Dec. 31, 2017).

<sup>29</sup> Express Scripts Annual Report (Form 10-K) (FYE Dec. 31, 2018).

170. At all relevant times, Express Scripts offered pharmacy benefit management services nationwide and maintained standard formularies that are used nationwide, including in Ohio. Those formularies included diabetes medications, including all identified in this Complaint.

171. Express Scripts purchases drugs directly from manufacturers for dispensing through its pharmacy network.

172. During certain years when large at-issue price increases occurred, including in 2013 and 2014, Express Scripts worked directly with OptumRx to negotiate Manufacturer Payments on behalf of OptumRx and its clients in exchange for preferred formulary placement. For example, in a February 2014 email released by the U.S. Senate in conjunction with its January 2021 report titled “Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug,” Eli Lilly describes a “Russian nested doll situation” in which Express Scripts was negotiating rebates on behalf of OptumRx related to the at-issue drugs for Cigna (which later became part of Express Scripts).<sup>30</sup>

173. At all relevant times, Express Scripts had express agreements with Defendants Novo Nordisk, Sanofi, and Eli Lilly related to the Manufacturer Payments paid by the Manufacturer Defendants to Express Scripts, as well as agreements related to the Manufacturers’ at-issue drugs sold through Express Scripts’ pharmacies.

174. **Defendant UnitedHealth Group, Inc.** is a corporation organized under the laws of Delaware with its principal place of business at 9900 Bren Road East, Minnetonka, Minnesota, 55343. It is a citizen of the State of Delaware and the State of Minnesota.

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<sup>30</sup> Grassley & Wyden, *supra* note 4; Letter from Joseph B. Kelley, Eli Lilly Vice President, Global Gov. Affairs, to Charles E. Grassley & Ron Wyden, S. Fin. Comm., [https://www.finance.senate.gov/imo/media/doc/Eli%20Lilly\\_Redacted%20v1.pdf](https://www.finance.senate.gov/imo/media/doc/Eli%20Lilly_Redacted%20v1.pdf) (last visited Jan. 13, 2023).

175. UnitedHealth Group, Inc. may be served through its registered agent: The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

176. UnitedHealth Group, Inc. is a diversified managed healthcare company. Its total revenues in 2021 exceeded \$287 billion, which was up more than \$30 billion from 2020. The company currently is ranked fifth on the Fortune 500 list.<sup>31</sup>

177. UnitedHealth Group, Inc. offers a spectrum of products and services including health insurance plans through its wholly owned subsidiaries and prescription drugs through its PBM, OptumRx.

178. Over one-third of the overall revenues of UnitedHealth Group come from OptumRx, which operates a network of more than 67,000 pharmacies.

179. UnitedHealth Group, through its executives and employees, is directly involved in the company policies that inform its PBM services and formulary construction, including with respect to the at-issue drugs and related to the Insulin Pricing Scheme. For example, UnitedHealth Group executives structure, analyze, and direct the company's overarching policies, including with respect to PBM and mail-order services, as a means of maximizing profitability across the corporate family.

180. UnitedHealth Group's Sustainability Report states that "OptumRx works directly with pharmaceutical manufacturers to secure discounts that lower the overall cost of medications and create tailored formularies – or drug lists – to ensure people get the right medications. [UnitedHealth Group] then negotiate[s] with pharmacies to lower costs at the point of sale . . . [UnitedHealth Group] also operate[s] [mail order

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<sup>31</sup> UnitedHealth Group, Inc. Annual Report (Form 10-K) (FYE Dec. 31, 2021).

pharmacies] . . . . [UnitedHealth Group] work[s] directly with drug wholesalers and distributors to ensure consistency of the brand and generic drug supply, and a reliance on that drug supply.”

181. In addition to being a PBM and a mail-order pharmacy, UnitedHealth Group owns and controls a major health insurance company, UnitedHealthcare. As a result, UnitedHealth Group controls the health plan/insurer, the PBM, and the mail-order pharmacies utilized by more than 26 million UnitedHealthcare members in the United States, including in Ohio. UnitedHealth Group controls the entire drug-pricing chain for these 26 million Americans.

182. UnitedHealth Group’s conduct had a direct effect in Ohio and damaged Plaintiff.

183. UnitedHealth Group states in its annual reports that UnitedHealth Group “utilizes Optum’s capabilities to help coordinate patient care, improve affordability of medical care, analyze cost trends, manage pharmacy benefits, work with care providers more effectively and create a simpler consumer experience.” Its most recent annual report states plainly that it is “involved in establishing the prices charged by retail pharmacies, determining which drugs will be included in formulary listings and selecting which retail pharmacies will be included in the network offered to plan sponsors’ members ....” As of December 31, 2021, “total pharmaceutical manufacturer rebates receivable included in other receivables in the Consolidated Balance Sheets amounted to \$7.2 billion [2021] and \$6.3 billion [2020].”<sup>32</sup>

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<sup>32</sup> UnitedHealth Group Annual Report (Form 10-K) (FYE Dec. 31, 2018); UnitedHealth Group Annual Report (Form 10-K, Exhibit 21) (FYE Dec. 31, 2021).



184. **Defendant Optum, Inc.** is a Delaware corporation with its principal place of business located in Eden Prairie, Minnesota. Optum, Inc. is a health services company managing subsidiaries that administer pharmacy benefits, including Defendant OptumRx, Inc.<sup>33</sup> It is a citizen of the State of Delaware and the State of Minnesota.

185. Optum, Inc. may be served through its registered agent: The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

186. Optum, Inc. is directly involved, through its executives and employees, in the company policies that inform its PBM services and formulary construction, including with respect to the at-issue drugs and related to the Insulin Pricing Scheme, which had a direct effect in Ohio and damaged Plaintiff.

187. For example, according to Optum Inc.'s press releases, Optum, Inc. is "UnitedHealth Group's information and technology-enabled health services business platform serving the broad healthcare marketplace, including care providers, plan sponsors, payors, life sciences companies and consumers." In this role, Optum, Inc. is directly responsible for the "business units – OptumInsight, OptumHealth and OptumRx" and the CEOs of all these companies report directly to Optum, Inc. regarding their policies, including those that inform the at-issue formulary construction and mail-order activities.

188. **Defendant OptumRx, Inc.** is a California corporation with its principal place of business at 2300 Main Street, Irvine, California, 92614. It is a citizen of the State of California.

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<sup>33</sup> UnitedHealth Group Annual Report (Form 10-K, Exhibit 21) (FYE Dec. 31, 2018).

189. OptumRx, Inc. operates as a subsidiary of OptumRx Holdings, LLC, which in turn operates as a subsidiary of Defendant Optum, Inc.

190. OptumRx, Inc. is and has since 2011 been registered to do business in the State of Ohio. OptumRx, Inc. may be served directly at OptumRx, Inc., 2300 Main Street, MS CA134-050, Irvine, California 92614.

191. OptumRx, Inc. holds at least two pharmacy licenses in Ohio.

192. During the relevant period, OptumRx, Inc. provided the PBM and mail-order pharmacy services in Ohio that gave rise to and implemented the Insulin Pricing Scheme, which damaged payors.

193. Defendant **OptumInsight, Inc. (“OptumInsight”)** is a Delaware corporation with its principal place of business located in Eden Prairie, Minnesota. It is a citizen of the State of Delaware and the State of Minnesota.

194. OptumInsight, Inc. is and has since 1998 been registered to do business in Ohio. OptumRx, Inc. may be served through its registered agent: CT Corporation System, 4400 Easton Commons Way, Suite 125, Columbus, Ohio 43219.

195. OptumInsight is an integral part of the Insulin Pricing Scheme and, during the relevant period, coordinated directly with the Manufacturer Defendants in furtherance of the conspiracy. OptumInsight analyzed data and other information from the Manufacturer Defendants to advise the other Defendants with regard to the profitability of the Insulin Pricing Scheme to the benefit of all Defendants.

196. As a result of numerous interlocking directorships and shared executives, UnitedHealth Group, OptumRx Holdings, LLC and Optum, Inc. are directly involved in the conduct of and control OptumInsight’s and OptumRx’s operations, management and

business decisions related to the at-issue formulary construction, negotiations, and mail-order pharmacy services. For example:

- a. These parent and subsidiaries have common officers and directors, including:
  - Andrew Witty is the CEO and on the Board of Directors for UnitedHealth Group and previously served as CEO of Optum, Inc.;
  - Dirk McMahon is President and COO of UnitedHealth Group Inc. He served as President and COO of Optum from 2017 to 2019, and as CEO of OptumRx from 2011 to 2014;
  - John Rex has been an Executive Vice President and CFO of UnitedHealth Group Inc. since 2016 and previously served in the same roles at Optum beginning in 2012;
  - Dan Schumacher is Chief Strategy and Growth Officer at UnitedHealth Group Inc. and is CEO of Optum Insight, having previously served as president of Optum, Inc.;
  - Terry Clark is a senior vice president and has served as Chief Marketing Officer at UnitedHealth Group since 2014 while also serving Chief Marketing and Customer Officer for Optum;
  - Tom Roos has served since 2015 as SVP and Chief Accounting Officer for UnitedHealth Group Inc. and Optum, Inc.;
  - Heather Cianfrocco joined UnitedHealth Group in 2008 and has held numerous leadership positions within the company. Today, she is CEO of OptumRx;
  - Peter Gill has served as SVP and Treasurer for UnitedHealth Group, Inc. and also as Treasurer at OptumRx, Inc.;
  - John Santelli led Optum Technology, the technology division of Optum, Inc., serving the broad customer base of Optum and UnitedHealthcare and also served as UnitedHealth Group's Chief Information Officer;
  - Eric Murphy, now retired, was the Chief Growth and Commercial Officer for Optum, Inc. and also CEO of OptumInsight beginning in 2017.
- b. UnitedHealth Group directly or indirectly owns all the stock of Optum, Inc., OptumRx, Inc., and OptumInsight.

- c. The UnitedHealth Group corporate family does not operate as separate entities. The public filings, documents, and statements of UnitedHealth Group present its subsidiaries, including Optum, Inc., OptumRx, Inc., and OptumInsight as divisions, departments or “segments” of a single company that is “a diversified family of businesses” that “leverages core competencies” to “help[] people live healthier lives and helping make the health system work better for everyone.” The day-to-day operations of this corporate family reflect these public statements. These entities are a single business enterprise and should be treated as such as to all legal obligations detailed in this Complaint.<sup>34</sup>
- d. All the executives of Optum, Inc., OptumRx, Inc., and OptumInsight ultimately report to the executives, including the CEO, of UnitedHealth Group.
- e. As stated above, UnitedHealth Group’s executives and officers are directly involved in the policies and business decisions of Optum, Inc., OptumRx, Inc., and OptumInsight that gave rise to Plaintiff’s claims.

197. Collectively, Defendants UnitedHealth Group, Inc., OptumRx, Inc., OptumInsight, and Optum, Inc., including all predecessor and successor entities, are referred to as “OptumRx.”

198. OptumRx is named as a Defendant in its capacities as a PBM and mail-order pharmacy.

199. OptumRx is a pharmacy benefit manager and, as such, coordinates with Novo Nordisk, Eli Lilly, and Sanofi regarding the price of the at-issue diabetes

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<sup>34</sup> UnitedHealth Group, Quarterly Report (Form 10-Q) (FQE Mar. 31, 2017).

medications, as well as for the placement of these firms' diabetes medications on OptumRx's drug formularies.

200. OptumRx provides pharmacy care services to more than 65 million people in the nation through a network of more than 67,000 retail pharmacies and multiple delivery facilities. It is one of UnitedHealth Group Inc.'s "four reportable segments" (along with UnitedHealthcare, Optum Health, and Optum Insight). In 2021, OptumRx "managed \$112 billion in pharmaceutical spending, including \$45 billion in specialty pharmaceutical spending."<sup>35</sup>

201. In 2018, OptumRx managed more than \$91 billion in pharmaceutical spending, representing 23% of the PBM market in the United States. OptumRx's 2018 revenue was \$69 billion.<sup>36</sup>

202. In 2019, OptumRx managed more than \$96 billion in pharmaceutical spending, with revenue of \$74 billion. By 2021, it had risen to \$91.3 billion.<sup>37</sup>

203. At all relevant times, OptumRx derived substantial revenue providing pharmacy benefits in Ohio.

204. At all relevant times, OptumRx offered pharmacy benefit management services nationwide and maintained standard formularies that are used nationwide, including in Ohio. Those formularies included diabetes medications, including those at issue in this action. OptumRx purchased drugs directly from manufacturers for dispensing through its pharmacy network.

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<sup>35</sup> UnitedHealth Group Annual Report (Form 10-K) (FYE Dec. 31, 2021).

<sup>36</sup> *Id.*

<sup>37</sup> *Id.*; UnitedHealth Group Annual Report (Form 10-K) (FYE Dec. 31, 2019).

205. At all relevant times, and contrary to its express representations, OptumRx knowingly insisted that its payor clients use the false list prices produced by the Insulin Pricing Scheme as the basis for reimbursement of the at-issue drugs.

206. At all relevant times, OptumRx concealed its critical role in the generation of those false list prices.

207. In its capacity as a mail-order pharmacy with a contracted network of retail pharmacies, OptumRx received payments from payors for, and set the out-of-pocket price paid for, the at-issue drugs based on the falsely inflated prices produced by the Insulin Pricing Scheme.

208. At all relevant times, OptumRx dispensed the at-issue medications nationwide and in Ohio through its mail-order and retail pharmacies and derived substantial revenue from these activities in Ohio.

209. OptumRx purchases drugs produced by the Manufacturer Defendants, including the at-issue diabetes medications, for dispensing through its mail-order pharmacies and network of retail pharmacies.

210. At all relevant times, OptumRx had express agreements with Defendants Novo Nordisk, Sanofi, and Eli Lilly related to the Manufacturer Payments paid by the Manufacturer Defendants to OptumRx, as well as agreements related to the Manufacturers' at-issue drugs sold through OptumRx pharmacies.

211. As set forth above, CVS Caremark, OptumRx, and Express Scripts are referred to collectively as the "PBM Defendants."

### **III. JURISDICTION AND VENUE**

#### **A. Subject-Matter Jurisdiction**

212. This Court has subject-matter jurisdiction pursuant to 28 U.S.C. § 1331 and pursuant to 18 U.S.C. § 1964(c) because this action alleges violations of the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. § 1962. This Court also has supplemental jurisdiction over the state law claims in this action pursuant to 28 U.S.C. § 1367.

#### **B. Personal Jurisdiction**

213. This Court has personal jurisdiction over each Defendant. Each Defendant: (1) transacts business and/or is admitted to do business within Ohio; (2) maintains substantial contacts in Ohio, and (3) committed the violations of Ohio statutes, federal statutes, and common law at issue in this action in whole or part within the State of Ohio. This action arises out of and relates to each Defendant's contacts with this forum.

214. The Insulin Pricing Scheme has been directed at and has had the foreseeable and intended effect of causing injury to persons residing in, located in, or doing business in Ohio, including Plaintiff. All transactions at issue occurred in the State of Ohio and/or involved Ohio residents.

215. Each Defendant purposefully availed itself of the privilege of doing business within this state, including within this district and division; and each derived substantial financial gain from doing so. These continuous, systematic, and case-related business contacts—including the tortious acts described herein—are such that each Defendant should reasonably have anticipated being brought into this Court.

216. Each Defendant submitted itself to jurisdiction through pervasive marketing; encouraging the use of its services; and its purposeful cultivation of profitable

relationships in the State of Ohio and within this forum. Each had direct interactions with Plaintiff concerning drug pricing.

217. In short, each Defendant has systematically served a market in Ohio relating to the Insulin Pricing Scheme and has caused injury in Ohio such that there is a strong relationship among Defendants, this forum, and the litigation.

218. This Court has personal jurisdiction over all Defendants pursuant to Fed. R. Civ. P. 4(k)(1)(A) because they would be subject to the jurisdiction of a court of general jurisdiction in Ohio.

219. This Court also has personal jurisdiction over all Defendants under 18 U.S.C. § 1965(b). This Court may exercise nationwide jurisdiction over the named Defendants where the “ends of justice” require national service and Plaintiff demonstrates national contacts. The interests of justice require that Plaintiff be allowed to bring all members of the nationwide RICO enterprise before the Court in a single action for a single trial.

### **C. Venue**

220. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b) and (c), because each Defendant transacts business in, is found in, and/or has agents in this District, and because a substantial part of the events or omissions giving rise to this action took place, or had their ultimate injurious impact, within this District. In particular, at all times during the relevant period, Defendants provided pharmacy benefit services, provided mail-order pharmacy services, employed sales representatives, promoted and sold diabetes medications and published prices of the at issue drugs in this District and caused injury to Plaintiff in this District.

221. Venue is proper in this District pursuant to 18 U.S.C. § 1965, because all Defendants reside, are found, have an agent, or transact their affairs in this District, and



the ends of justice require that any Defendant residing elsewhere be brought before this Court.

#### IV. ADDITIONAL FACTUAL ALLEGATIONS

##### A. Diabetes and Insulin Therapy

###### *The Diabetes Epidemic*

222. Diabetes occurs when a person's blood glucose is too high. In people without diabetes, the pancreas secretes the hormone insulin, which controls the rate at which food is converted to blood glucose. When insulin is lacking or when cells stop responding to insulin, blood sugar stays in the bloodstream. Over time, this can cause serious health problems, including heart disease, blindness, and kidney disease and ultimately lead to premature death.

223. There are two basic types of diabetes—Type 1 and Type 2. Roughly 90-95% of diabetics have Type 2 diabetes, which develops when one does not produce enough insulin or has become resistant to the insulin one produces. While Type 2 patients can initially be treated with tablets, in the long term most patients must switch to insulin injections.

224. Diabetes has been on the rise for decades. In 1958, only 1.6 million Americans had diabetes. By the turn of the century, however, that number had grown to over ten million. Fourteen years later, the number had tripled. Today, more than 37 million Americans—approximately 11% of the country—live with the disease.

225. The prevalence of diabetes in Ohio has increased as well. More than one million adult Ohioans—or 12.4%—have been diagnosed as diabetic.<sup>38</sup>

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<sup>38</sup> Ohio Dept. of Health, Diabetes, <https://diabetes.org/sites/default/> <https://odh.ohio.gov/know-our-programs/diabetes/diabetes> (last visited June 30, 2023).

*Insulin: A Century-Old Drug*

226. Despite its potential lethality, diabetes is highly treatable. Patients able to follow a prescribed treatment plan consistently avoid severe health complications associated with the disease.

227. Unlike many high-burden diseases, treatment for diabetes has been available for almost a century.

228. In 1922, Frederick Banting and Charles Best, while working at the University of Toronto, pioneered a technique for removing insulin from an animal pancreas that could then be used to treat diabetes. Banting and Best obtained a patent and then sold it to the University of Toronto for \$1 (equivalent to \$18 today), explaining that “[w]hen the details of the method of preparation are published anyone would be free to prepare the extract, but no one could secure a profitable monopoly.”<sup>39</sup>

229. After purchasing the patent, the University of Toronto contracted with Defendants Eli Lilly and Novo Nordisk to scale its production. Under this arrangement, Eli Lilly and Novo Nordisk were allowed to apply for patents on variations to the manufacturing process.

230. The earliest insulin was derived from animals and, until the 1980s, was the only treatment for diabetes. While effective, animal-derived insulin can be allergenic. In 1982, synthetic insulin—known as human insulin because it mimics the insulin humans make—was developed by Defendant Eli Lilly. Eli Lilly marketed this insulin as Humulin. The development of human insulin benefited heavily from government and non-profit funding through the National Institutes of Health and the American Cancer Society.

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<sup>39</sup> M. Bliss, *The Discovery of Insulin* (2013).

231. In the mid-1990s, Eli Lilly introduced the first analog insulin—a laboratory-grown and genetically altered insulin. Analogs are slight variations on human insulin that make the injected treatment act more like the insulin naturally produced and regulated by the body and more quickly lower blood sugar. Eli Lilly released this analog in 1996 under the brand name Humalog at a cost of \$21 per vial (equivalent to \$40 in 2022).

232. Other rapid-acting analogs include Novo Nordisk’s Novolog and Sanofi’s Apidra, which have similar profiles. Rapid-acting insulins are used in combination with longer-acting insulins, such as Sanofi’s Lantus and Novo Nordisk’s Levemir.

233. Manufacturer Defendants introduced these rapid-acting and long-acting analog insulins between 1996 and 2007.

234. In 2015, Sanofi introduced Toujeo, another long-acting insulin also similar to Lantus; Toujeo, however, is highly concentrated, reducing injection volume as compared to Lantus.

235. In December 2015, Eli Lilly introduced Basaglar—a long-acting insulin that is biologically similar to Sanofi’s Lantus.

236. Even though insulin was first extracted 100 years ago, and despite its profitability, only Defendants Eli Lilly, Novo Nordisk, and Sanofi manufacture insulin for the United States market. This did not occur by chance.

237. Many of the at-issue medications are now off-patent. The Manufacturers maintain market domination through patent “evergreening.” Drugs usually face generic competition when their twenty-year patents expire. While original insulin formulas may technically be available for generic use, the Manufacturers “stack” patents around the original formulas, making new competition exceedingly costly and risky. For example, Sanofi has filed more than seventy patents on Lantus—more than 95% were filed after the

drug was approved by the FDA—potentially providing more than three additional decades of patent “protection” for the drug. The market thus remains concentrated.

*The Current Insulin Landscape*

238. While insulin today is generally safer and more convenient to use than when originally developed in 1922, there remain questions about whether the overall efficacy of insulin has significantly improved over the last twenty years.

239. For example, while long-acting analogs may have certain advantages over human insulins, such as affording more flexibility around mealtime planning, it has yet to be shown that analogs lead to better long-term outcomes. Recent work suggests that older human insulins may work just as well as newer analog insulins for patients with Type 2 diabetes.

240. Moreover, all insulins at issue in this case have either been available in the same form since the late 1990s/early 2000s or are biologically equivalent to insulins that were available then.

241. As Dr. Kasia Lipska, a Yale researcher, explained in the Journal of the American Medical Association:

We’re not even talking about rising prices for better products here. I want to make it clear that we’re talking about rising prices for the same product . . . there’s nothing that’s changed about Humalog. It’s the same insulin that’s just gone up in price and now costs ten times more.<sup>40</sup>

242. Production costs have decreased in recent years. A September 2018 study in BMJ Global Health calculated that, based on production costs, a reasonable and profitable price for a year’s supply of human insulin is between \$48 and \$71 per person

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<sup>40</sup> Natalie Shure, *The Insulin Racket*, American Prospect (June 24, 2019), <https://prospect.org/health/insulin-racket/> (last visited Jan. 14, 2023).

(and between \$78 and \$133 for analog insulins). Another recent study found that the Manufacturers could be profitable charging as little as \$2 per vial.

243. Yet diabetics spent an average of \$5,705 for insulin in 2016. According to a 2020 RAND report, the 2018 list price per vial across all forms of insulin was just \$14.40 in Japan, \$12.00 in Canada, \$11.00 in Germany, \$9.08 in France, \$7.52 in the United Kingdom, and less than \$7.00 in Australia. In the U.S. it was \$98.70.

244. While R&D costs often contribute significantly to the price of a drug, the initial basic insulin research—original drug discovery and patient trials—occurred 100 years ago. Even more recent costs like developing a recombinant DNA fermentation process and creating insulin analogs, were incurred decades ago. In recent years, most R&D costs have been incurred in connection with the development of new insulin-related devices and equipment, not in connection with the drug formulations themselves.

245. The Manufacturer Defendants recently announced limited pricing changes and out-of-pocket limits.

246. On March 1, 2023, Eli Lilly announced that it would reduce the prices of some insulin medications, capping those prices at \$35 per month, with additional reductions to follow later in the year. Eli Lilly promised to list its Lispro injection at \$25 per vial effective May 1, 2023, and reduce the price of Humalog and Humulin injections by 70% starting in the fourth quarter of 2023. The price reductions are limited to these medications. These price cuts suggest that prices before March 2023 were not tied to costs of research and development or other necessary and unavoidable expenses.

247. On March 14, 2023, Novo Nordisk announced that it would lower the U.S. list prices of several insulin products by up to 75%—specifically, Levemir, Novolin, NovoLog, and NovoLog Mix 70/30. Novo Nordisk will also reduce the list price of

unbranded biologics. The price reductions are limited to these medications and do not apply to other Novo Nordisk diabetes medications. These changes will go into effect on January 1, 2024, and suggest that previous prices for these medications were not tied to costs of research and development or other necessary and unavoidable expenses.

248. On March 16, 2023, Sanofi announced that it would cap the out-of-pocket cost of its most popular insulin, Lantus, at \$35 per month for people with private insurance, effective January 1, 2024, and lower the list price of Lantus by 78% and Apidra, its short-acting insulin, by 70%. Sanofi had already capped the price of Lantus at \$35 for patients without insurance. The price reductions to date are limited to these medications and do not apply to other Sanofi diabetes medications. Sanofi's reductions, like Eli Lilly's and Novo Nordisk's, suggest that the earlier prices of Sanofi's medications were not tied to costs of research and development or other necessary and unavoidable expenses.

249. These three announcements (the "Price Cuts") are prospective and do not mitigate damages already incurred by payors like Plaintiff.

250. The Price Cuts are limited and do not encompass all at-issue medications. As part of the Insulin Pricing Scheme, the PBMs provide preferred formulary placement to the most expensive insulins based on list prices. Accordingly, the Insulin Pricing Scheme will proceed, with the PBMs continuing to target the most expensive at-issue medications, which will likely be the at-issue medications not included in the Price Cuts.

251. The Price Cuts are insufficient. An Eli Lilly spokeswoman has represented that the current list price for a 10-milliliter vial of the fast-acting, mealtime insulin Humalog will drop to \$66.40 from \$274.70, and a 10-milliliter vial of Humulin will fall

from \$148.70 to \$44.61.<sup>41</sup> These prices far exceed the Manufacturers' costs and remain significantly higher than the prices for the same and similar drugs in other countries.

*Insulin Adjuncts: Type 2 Medications*

252. Over the past decade, the Manufacturer Defendants released a number of non-insulin medications that help control insulin levels. In 2010, Novo Nordisk released Victoza, and over the next seven years Eli Lilly released Trulicity, Sanofi released Soliqua, and Novo Nordisk followed up with Ozempic.<sup>42</sup> Each of these drugs can be used in conjunction with insulins to control diabetes.

253. The following is a list of diabetes medications at issue in this lawsuit:

**Table 1: Diabetes medications at issue in this case**

Insulin Type	Action	Name	Company	FDA Approval	Current/Recent List Price
Human	Rapid-Acting	Humulin R	Eli Lilly	1982	\$178 (vial)
		Humulin R 500	Eli Lilly	1982	\$1784 (vial) \$689 (pens)
		Novolin R	Novo Nordisk	1991	\$165 (vial) \$312 (pens)
	Intermediate	Humulin N	Eli Lilly	1982	\$178 (vial) \$566 (pens)
		Humulin 70/30	Eli Lilly	1989	\$178 (vial) \$566 (pens)
		Novolin N	Novo Nordisk	1991	\$165 (vial) \$312 (pens)
		Novolin 70/30	Novo Nordisk	1991	\$165 (vial) \$312 (pens)

<sup>41</sup> Tom Murphy, *Lilly plans to slash some insulin prices, expand cost cap*, AP News (Mar. 2, 2023) (available at <https://apnews.com/article/insulin-diabetes-humalog-humulin-prescription-drugs-eli-lilly-lantus-419db92bfe554894bdc9c7463f2f3183>)

<sup>42</sup> Victoza, Trulicity, and Ozempic are glucagon-like peptide-1 receptor agonists ("GLP-1") and mimic the GLP-1 hormone produced in the body. Soliqua is a combination long-acting insulin and GLP-1 drug.

Insulin Type	Action	Name	Company	FDA Approval	Current/Recent List Price
Analog	Rapid-Acting	Humalog	Eli Lilly	1996	\$342 (vial) \$636 (pens)
		Novolog	Novo Nordisk	2000	\$347 (vial) \$671 (pens)
		Apidra	Sanofi	2004	\$341 (vial) \$658 (pens)
	Long-Acting	Lantus	Sanofi	2000	\$340 (vial) \$510 (pens)
		Levemir	Novo Nordisk	2005	\$370 (vial) \$555 (pens)
		Basaglar (Kwikpen)	Eli Lilly	2015	\$392 (pens)
		Toujeo (Solostar)	Sanofi	2015	\$466 (pens) \$622 (max pens)
		Tresiba	Novo Nordisk	2015	\$407 (vial) \$610 (pens – 100u) \$732 (pens – 200u)
	Type 2 Medications	Trulicity	Eli Lilly	2014	\$1013 (pens)
		Victoza	Novo Nordisk	2010	\$813 (2 pens) \$1220 (3 pens)
		Ozempic	Novo Nordisk	2017	\$1022 (pens)
		Soliqua	Sanofi	2016	\$928 (pens)

## B. The Dramatic Rise in the Price of Diabetes Medications in the U.S.

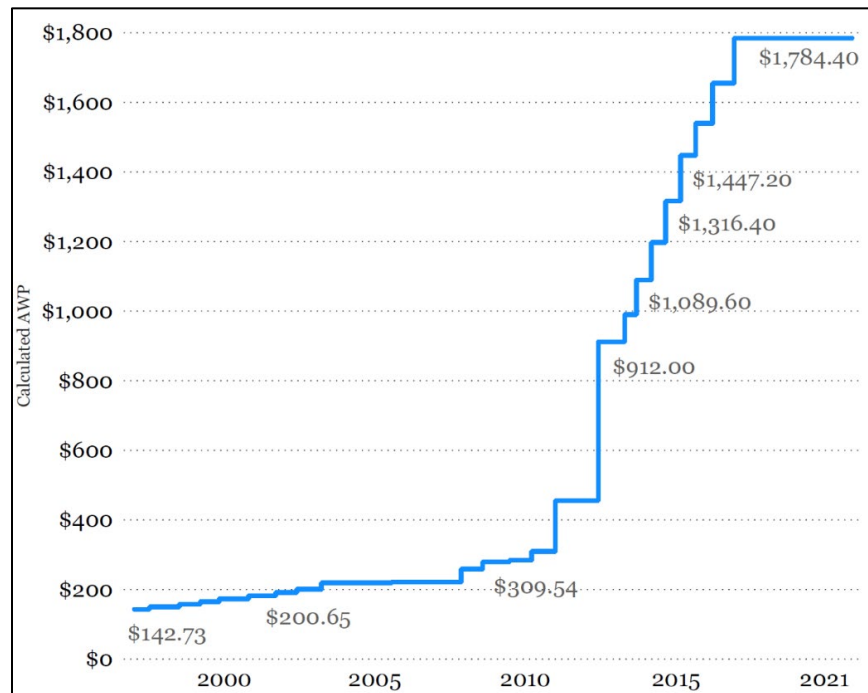
254. In the past twenty-five years, the list price of certain insulins has increased in some cases by more than 1000% (10x).

255. According to the U.S. Bureau of Labor Statistics, \$165 worth of consumer goods and services in 1997 dollars would, in 2021, have cost \$289 (1.75x).<sup>43</sup>

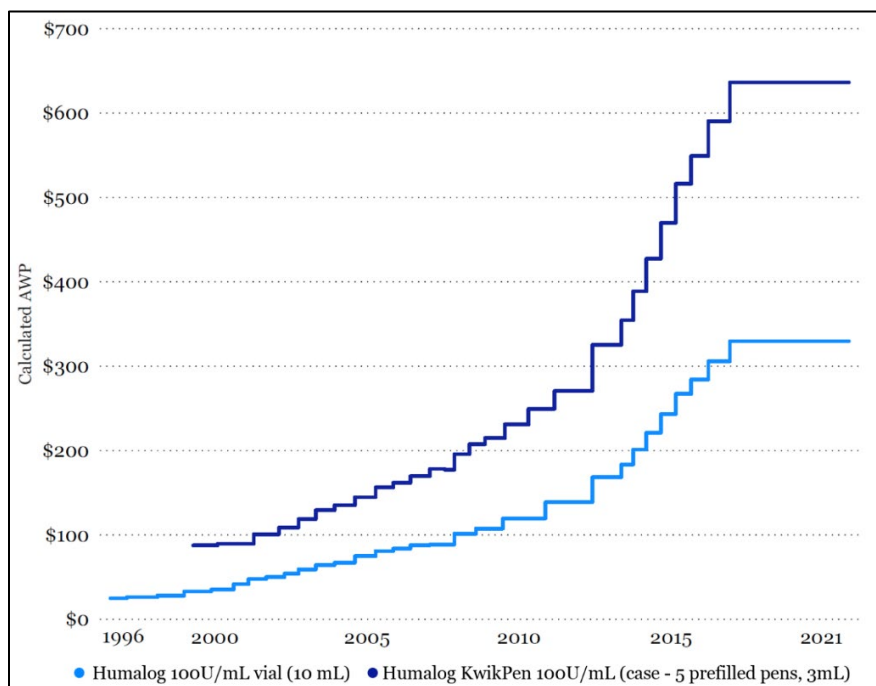
256. Since 1997, Eli Lilly has raised the list price of a vial of Humulin R (500U/mL) from \$165 to \$1784 in 2021 (10.8x). (Fig. 3.)

<sup>43</sup> [https://www.bls.gov/data/inflation\\_calculator.htm](https://www.bls.gov/data/inflation_calculator.htm) (last visited Jan. 3, 2023). The Consumer Price Index (CPI) measures “the average change over time in the prices paid by urban consumers for a market basket of consumer goods and services.” (<https://www.bls.gov/cpi/>).



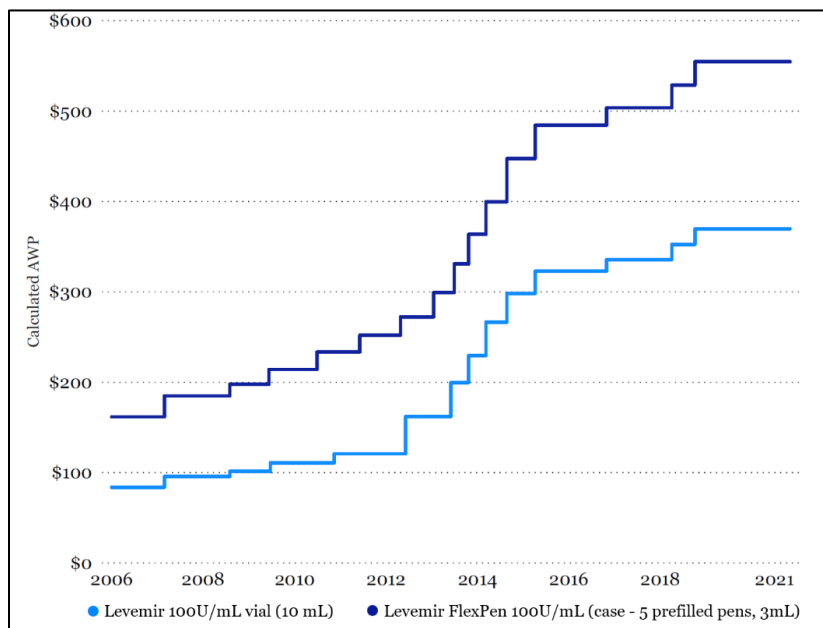
**Figure 3: Rising list prices of Humulin R (500U/mL), 1997-2021**

257. Since 1996, Eli Lilly has raised the price for a package of pens of Humalog from under \$100 to \$663 (6.6x) and from less than \$50 for a vial to \$342 (6.8x). (Fig. 4.)

**Figure 4: Rising list prices of Humalog vials and pens, 1996-2021**

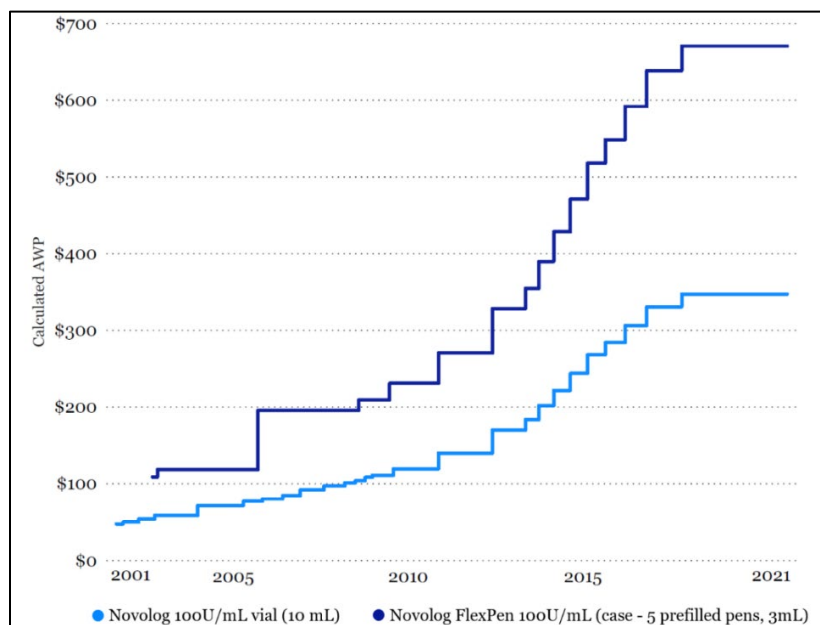
258. From 2006 to 2020, Novo Nordisk's Levemir rose from \$162 to \$555 (3.4x) for pens and from under \$100 to \$370 per vial (3.7x). (Fig. 5.)

**Figure 5: Rising list prices of Levemir, 2006-2021**



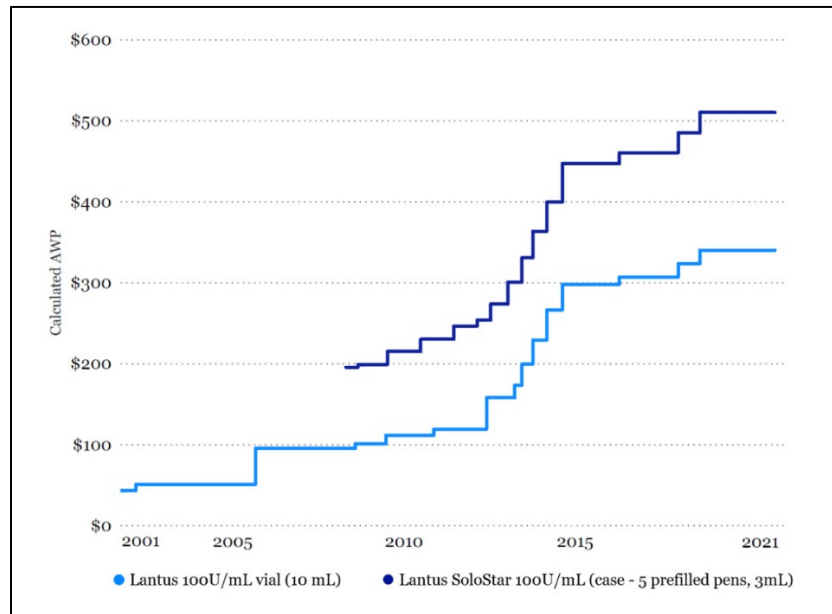
259. From 2002 to 2021, Novo Nordisk raised the list price of Novolog from \$108 to \$671 (6.2x) for a pack of pens and from under \$50 to \$347 (6.9x) for a vial. (Fig. 6.)

**Figure 6: Rising list prices of Novolog vials and pens, 2002-2021**



260. Defendant Sanofi kept pace as well. It manufactures a top-selling analog insulin—Lantus—which has been and remains a flagship brand for Sanofi. It has been widely prescribed nationally and within the State of Ohio, including to Plaintiff's Beneficiaries. Prices for Lantus have risen from less than \$200 in 2006, to over \$500 in 2020 (2.5x) for a package of pens and from less than \$50 to \$340 for a vial (6.8x). (Fig. 7.)

**Figure 7: Rising list prices of Lantus vials and pens, 2001-2021**



261. The Defendant Manufacturers' non-insulin diabetes medications have experienced similar recent price increases.

262. Driven by these price hikes, payors' and diabetics' spending on these drugs has steadily increased with totals in the tens of billions of dollars.

*The Defendant Manufacturers Increased Prices in Lockstep*

263. The timing of the price increases reveals that each Manufacturer Defendant not only dramatically increased prices for the at-issue diabetes treatments, but they did so in lockstep.

264. Between 2009 and 2015, for example, Sanofi and Novo Nordisk raised the

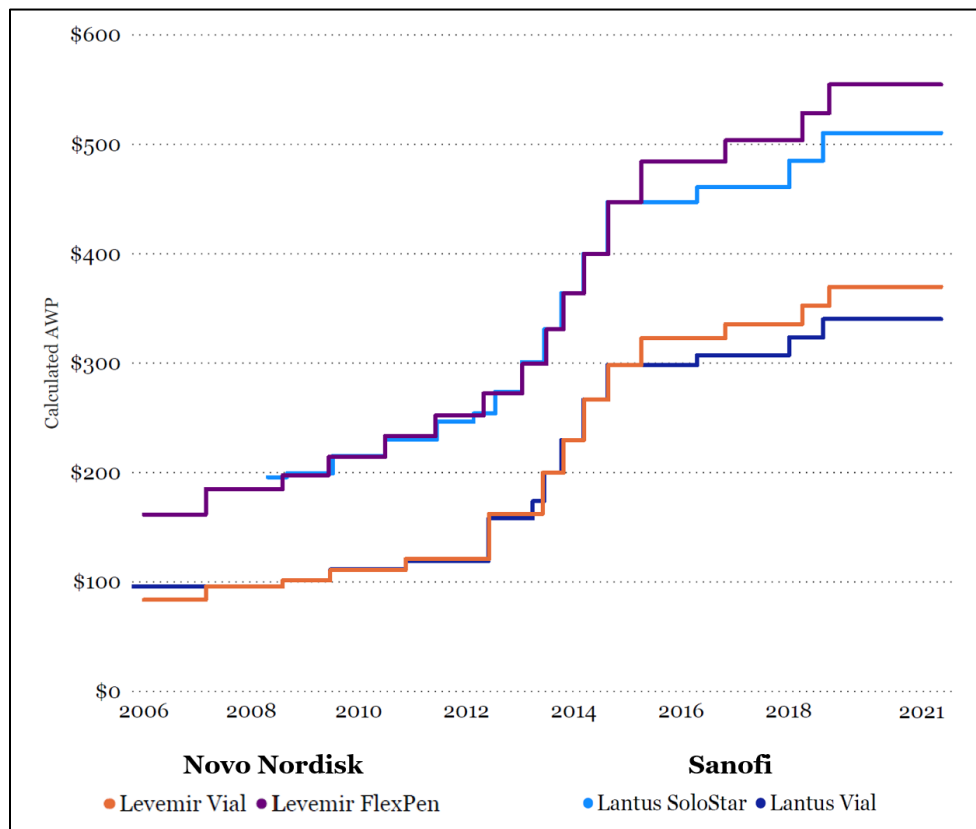
list prices of their insulins in tandem thirteen times, taking the same price increase down to the decimal point within days of each other, and sometimes within a few hours.<sup>44</sup>

265. This is known as “shadow pricing,” which communicates between competitors their intention not to price-compete against one another.

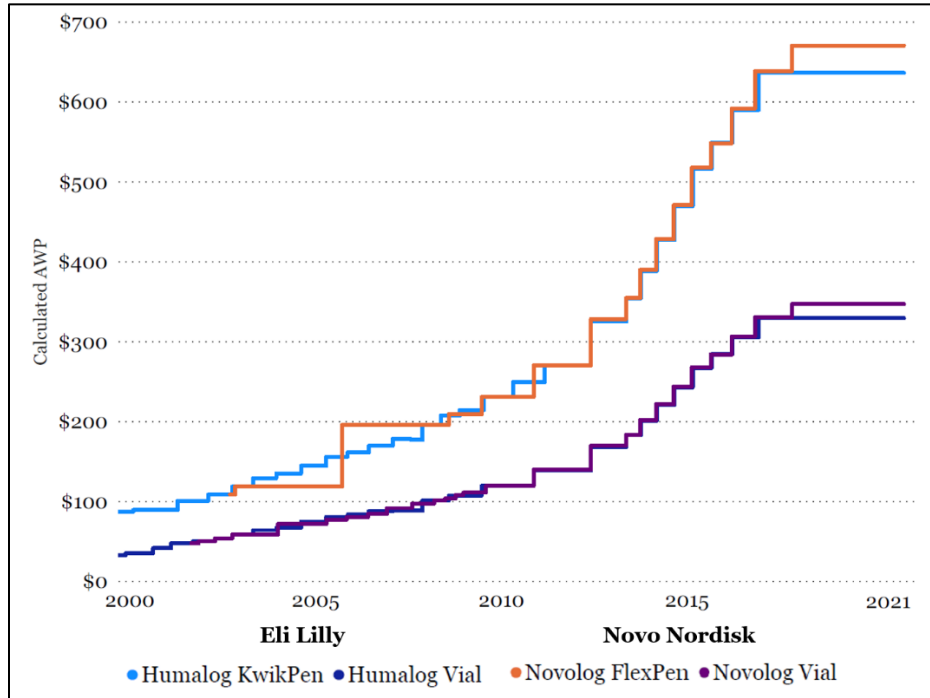
266. In 2016, Novo Nordisk and Sanofi’s lockstep increases for the at-issue drugs represented the highest drug price increases in the pharmaceutical industry.

267. Eli Lilly and Novo Nordisk have engaged in the same lockstep behavior with respect to their rapid-acting analog insulins, Humalog and Novolog. Figure 8 demonstrates this collusive behavior with respect to Lantus and Levemir. Figure 9 demonstrates this behavior with respect to Novolog and Humalog.

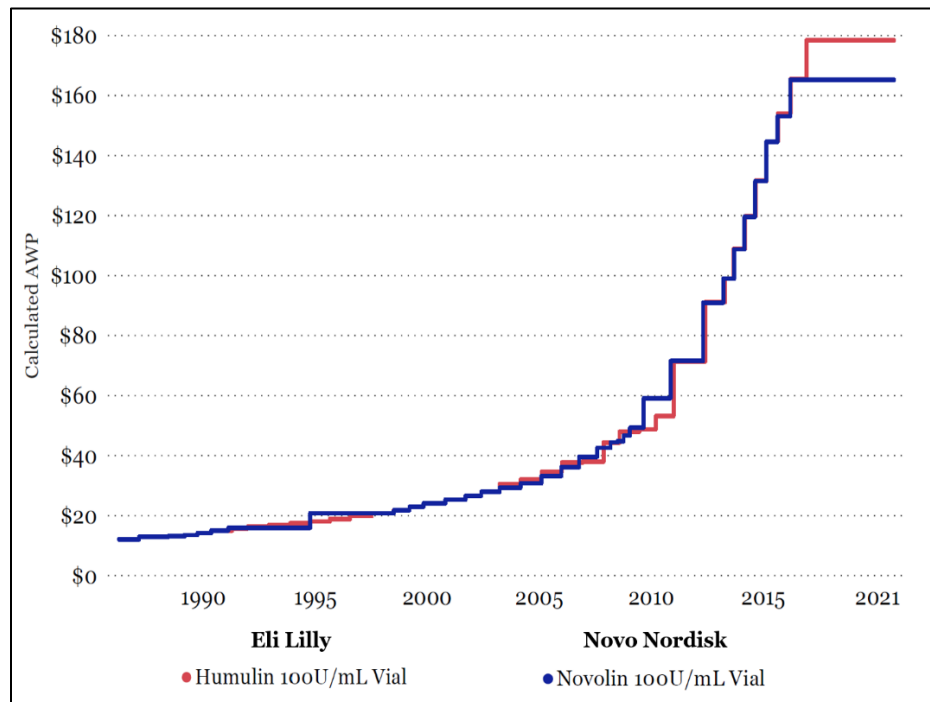
**Figure 8: Rising list prices of long-acting insulins**



<sup>44</sup> Grassley & Wyden, *supra* note 4.

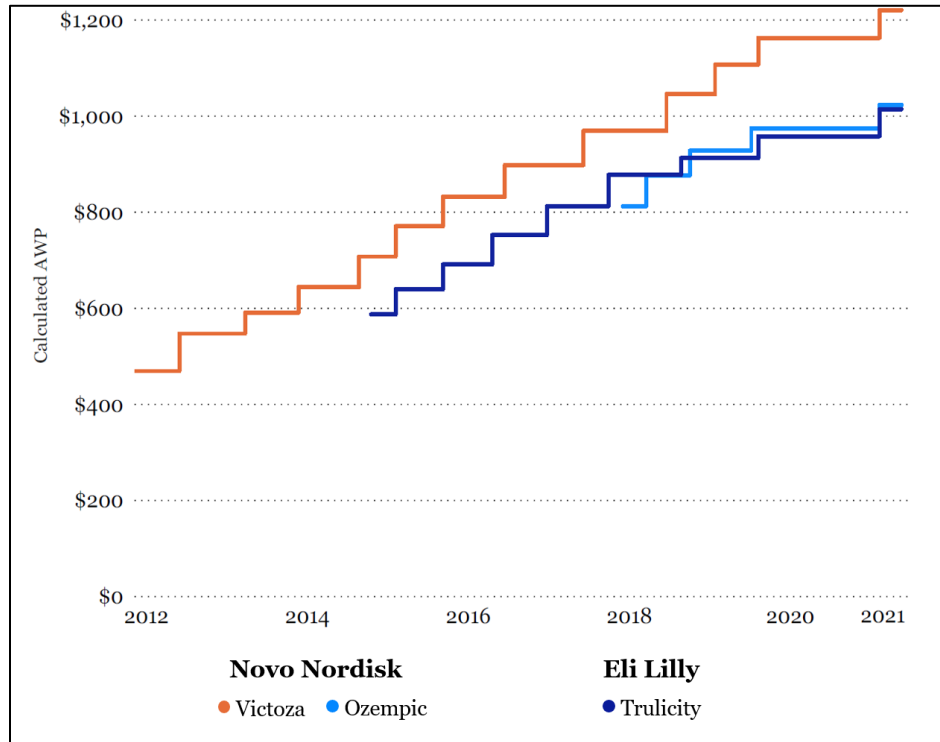
**Figure 9: Rising list prices of rapid-acting insulins**

268. Figure 10 below demonstrates this behavior with respect to the human insulins—Eli Lilly’s Humulin and Novo Nordisk’s Novolin.

**Figure 10: Rising list price increases for human insulins**

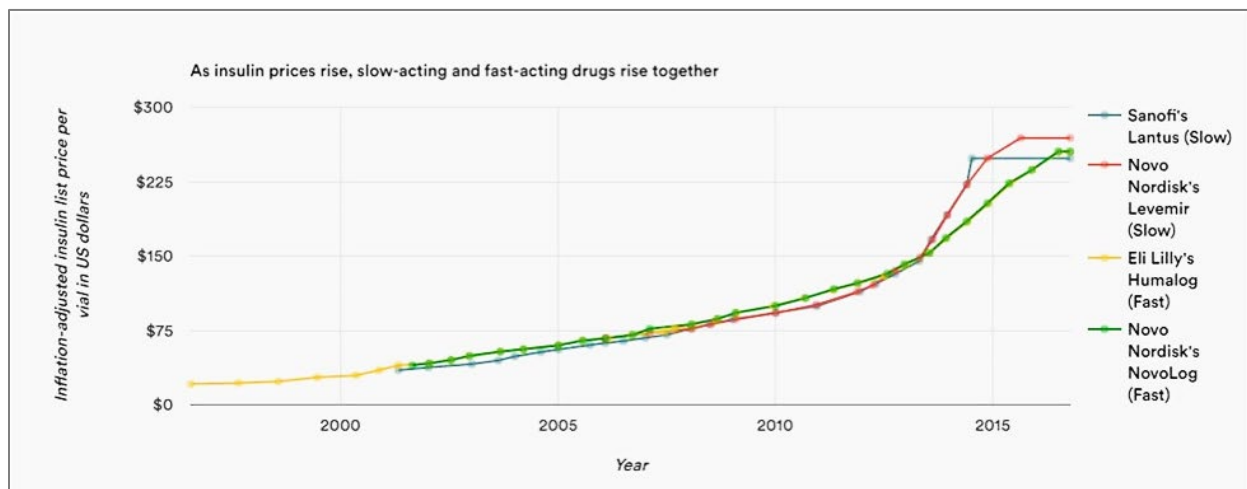
269. Figure 11 below demonstrates Defendants' lockstep price increases for their Type 2 drugs Trulicity, Victoza, and Ozempic.

**Figure 11: Rising list prices of Type 2 drugs**



270. Figure 12 below shows how, collectively, the Manufacturer Defendants have exponentially raised the prices of insulin products in near-perfect unison.

**Figure 12: Lockstep insulin price increases**



271. While the list prices for all the at-issue diabetes medications have increased dramatically, the net prices (i.e., the prices realized by the Manufacturers) have not.

272. Because of the Manufacturer Defendants' collusive price increases, nearly a century after the discovery of insulin, diabetes medications have become unaffordable for many diabetics.

### **C. The Pharmaceutical Payment and Supply Chain**

273. The prescription drug industry is comprised of a deliberately opaque network of entities engaged in multiple distribution and payment structures. These entities include manufacturers, wholesalers, pharmacies, payors, PBMs, and patients.

274. Given the complexities of the different parties involved in the pharmaceutical industry, pharmaceuticals are distributed in many ways. Generally speaking, branded prescription drugs, such as the at-issue diabetes medications, often are distributed in one of three ways: (1) from manufacturer to wholesaler (distributor), wholesaler to pharmacy, and pharmacy to patient, or (2) from manufacturer to mail-order pharmacy to patient; and (3) from manufacturer to mail-order pharmacy, mail-order pharmacy to self-insured payor, and then self-insured payor to patient.

275. The pharmaceutical industry, however, is unique in that the pricing chain is distinct from the distribution chain. The prices for the drugs distributed in the pharmaceutical chain are different for each participating entity: different actors pay different prices set by different entities for the same drugs. The unifying factor is that the price that each entity in the pharmaceutical chain pays for a drug is tied inexorably to the price set by the manufacturer. The pricing chain includes self-insured payors like Plaintiff paying PBMs directly. Defendant CVS Caremark routinely invoiced Plaintiff for the at-issue diabetes medications.

276. But there is no transparency in this pricing system. Typically, only a brand drug's list price—also known as its Average Wholesale Price (AWP) or the mathematically-related Wholesale Acquisition Cost (WAC)—is available.

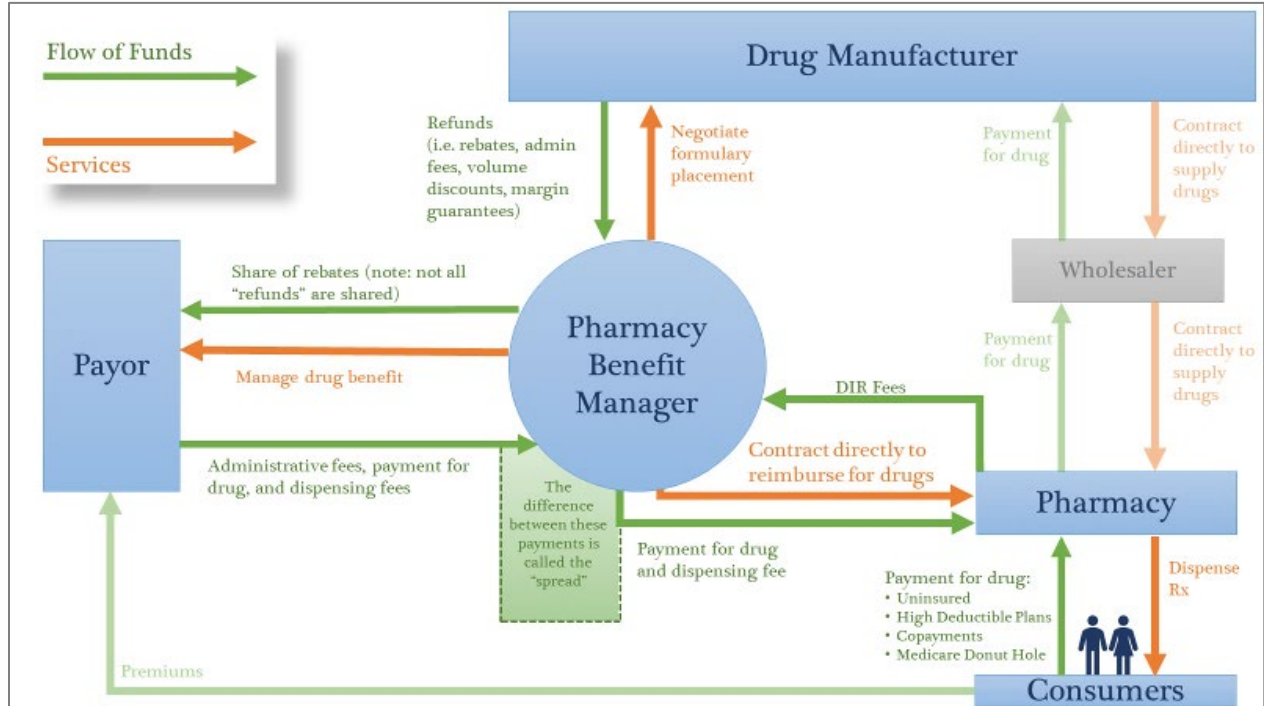
277. Manufacturers self-report AWP or other prices upon which AWP is based to publishing compendiums such as First DataBank, who then publish those prices.

278. As a direct result of the PBMs' conduct, AWP persists as the most commonly and continuously used list price in reimbursement and payment calculations and negotiations for both payors and patients.

#### D. The PBMs' Role in the Pharmaceutical Payment Chain

279. The PBMs are at the center of the convoluted pharmaceutical payment chain, as illustrated in Figure 13 below.

**Figure 13: Insulin distribution and payment chain**



280. The PBM Defendants develop drug formularies, process claims, create a network of retail pharmacies, set the prices in coordination with the Manufacturers that



the payor will pay for prescription drugs, and are paid by the payor to reimburse pharmacies for the drugs utilized by the payor's beneficiaries.

281. The PBMs also contract with a network of retail pharmacies. Pharmacies agree to dispense drugs to patients and pay fees back to the PBMs. The PBMs reimburse pharmacies for the drugs dispensed.

282. The PBM Defendants also own mail-order and specialty pharmacies, which purchase and take possession of prescription drugs, including those at issue here, and directly supply those drugs to patients by mail.

283. Often—including for the at-issue drugs—the PBM Defendants purchase drugs directly from the Manufacturers and distribute them directly to the patients.

284. Even where PBM-Defendant mail-order pharmacies purchase drugs from wholesalers, their costs are set by direct contracts with the manufacturers.

285. In addition, and of particular significance here, the PBM Defendants contract with drug manufacturers, including the Manufacturer Defendants. The PBMs extract from the Manufacturers rebates, fees, and other consideration that is paid back to the PBM, including the Manufacturer Payments related to the at-issue drugs.

286. Manufacturers also interact with the PBMs related to other services outside the scope of the Insulin Pricing Scheme, such as health and educational programs and patient and prescriber outreach with respect to drugs not at-issue in this Complaint.

287. These relationships place PBMs at the center of the flow of pharmaceutical money and allow them to exert tremendous influence over what drugs are available nationwide, including in Cleveland and throughout Ohio, on what terms, and at what prices.

288. Historically and today, PBMs:

- negotiate the price that payors pay for prescription drugs (based on prices generated by the Insulin Pricing Scheme);
- separately negotiate a different (and often lower) price that pharmacies in their networks receive for the same drug;
- set the amount in fees that the pharmacy pays back to the PBM for each drug sold (based on prices generated by the Insulin Pricing Scheme);
- set the price paid for each drug sold through their mail-order pharmacies (based on prices generated by the Insulin Pricing Scheme); and
- negotiate the amount that the Manufacturers pay back to the PBM for each drug sold (based on prices generated by the Insulin Pricing Scheme).

289. Yet, for the majority of these transactions, only the PBMs are privy to the amount that any other entity in this supply chain is paying or receiving for the same drugs. This lack of transparency affords Defendants the opportunity to extract billions of dollars from this payment and supply chain without detection.

290. In every interaction that the PBMs have within the pharmaceutical pricing chain, they stand to profit from the prices generated by the Insulin Pricing Scheme.

#### *The Rise of the PBMs in the Pharmaceutical Supply Chain*

291. At first, in the 1960s, PBMs functioned largely as claims processors. Over time, however, they have taken on an ever-expanding role as participants in pharmaceutical pricing and distribution chains.

292. One of the roles PBMs took on, as discussed above, was negotiating with drug manufacturers—ostensibly on behalf of payors. In doing so, PBMs affirmatively represented that they were using their leverage to drive down drug prices.

293. In the early 2000s, PBMs started buying pharmacies, thereby creating an additional incentive to collude with manufacturers to keep certain prices high.

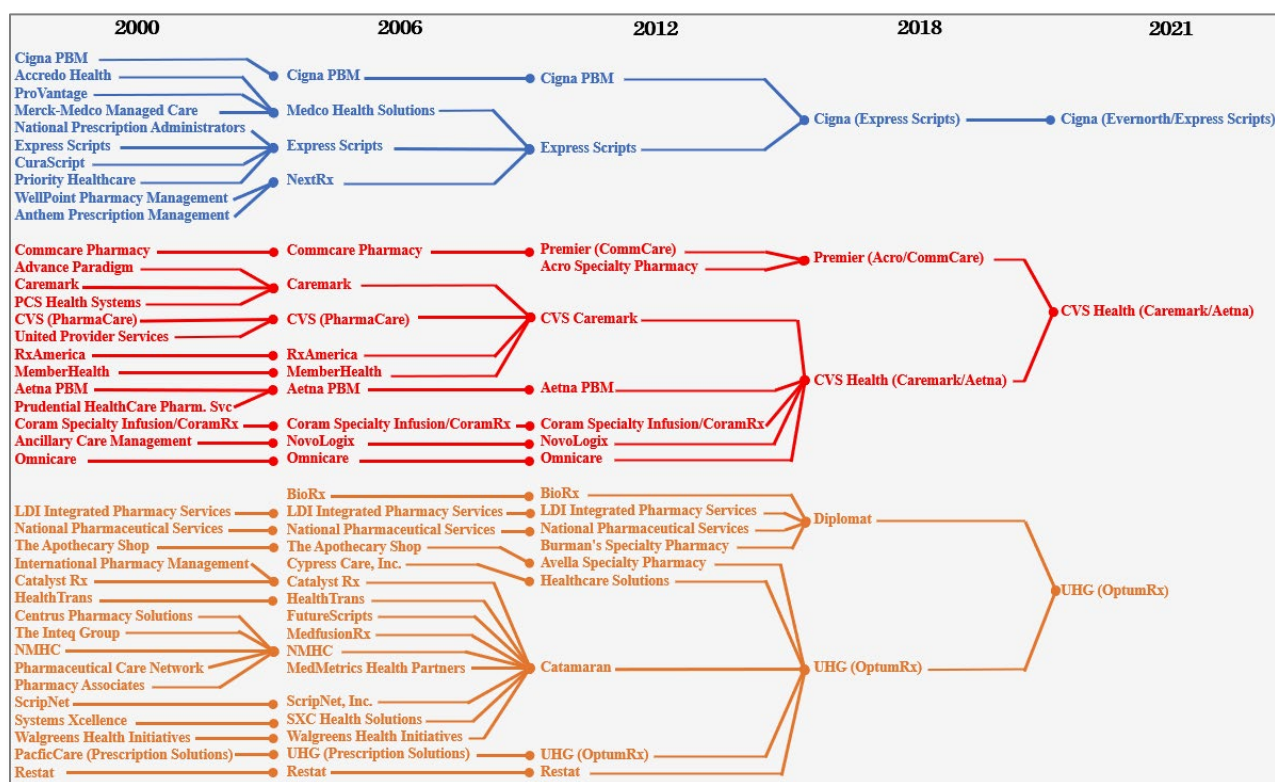
294. These perverse incentives still exist today with respect to both retail and

mail-order pharmacies housed within the PBMs' corporate families. Further recent consolidation in the industry has given PBMs disproportionate market power.

295. Nearly forty PBM entities combined into what are now the PBM Defendants, each of which now is affiliated with another significant player in the pharmaceutical chain, e.g., Express Scripts merged with Cigna; CVS bought Caremark, which now also owns Aetna; and UnitedHealth Group acquired OptumRx.

296. Figure 14 depicts this consolidation within the PBM market.

**Figure 14: PBM consolidation**



297. After merging with or acquiring all of their competitors, and now backed by multibillion-dollar corporations, the PBM Defendants have taken over the market in the past decade, controlling more than 80% of the market and managing pharmacy benefits for more than 270 million Americans.

298. Together, the PBM Defendants report more than \$300 billion in annual revenue.

299. The PBMs use this market consolidation and the resulting purchasing power as leverage when negotiating with other entities in the pharmaceutical pricing chain.

*The Insular Nature of the Pharmaceutical Industry*

300. The insular nature of the pharmaceutical industry has provided Defendants with ample opportunity for contact and communication with their competitors, as well as with the other PBM and Manufacturer Defendants, in order to devise and agree to the Insulin Pricing Scheme.

301. Each Manufacturer Defendant is a member of the industry-funded Pharmaceutical Research and Manufacturers of America (“PhRMA”) and has routinely communicated through PhRMA meetings and platforms in furtherance of the Insulin Pricing Scheme. According to PhRMA’s 2019 IRS Form 990, it received more than \$515 million in “membership dues.” All members are pharmaceutical companies.<sup>45</sup>

302. David Ricks (CEO of Eli Lilly), Paul Hudson (CEO of Sanofi), and Douglas Langa (President of Novo Nordisk and EVP of North American Operations), serve on the PhRMA Board of Directors and/or are part of the PhRMA executive leadership team.

303. The PBM Defendants also routinely communicate through direct interaction with their competitors and the Manufacturers at trade associations and industry conferences.

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<sup>45</sup> PhRMA 2019 Form 990, <https://projects.propublica.org/nonprofits/organizations/530241211/202043189349300519/full>; PhRMA, *About PhRMA*, <https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/A-C/About-PhRMA2.pdf> (last visited Jan. 4, 2023).

304. Each year during the relevant period, the main PBM trade association, the industry-funded Pharmaceutical Care Management Association (“PCMA”), held several yearly conferences, including its Annual Meeting and its Business Forum conferences.<sup>46</sup>

305. The PCMA is governed by PBM executives. As of January 2023, the board of the PCMA included Alan Lotvin (Executive Vice President of PBM Defendant CVS Health and President of CVS Caremark); Amy Bricker (then-President of PBM Defendant Express Scripts; now with CVS); and Heather Cianfrocco (CEO of PBM Defendant OptumRx). As of March 2023, the PCMA board includes PBM-affiliated members Adam Kautzner (President of Express Scripts); David Joyner (EVP at CVS Health), and Heather Cianfrocco (CEO of OptumRx).

306. All PBM Defendants are members of—and due to their leadership positions, have substantial control over—the PCMA.

307. The Manufacturer Defendants are affiliate members of the PCMA.

308. Every year, high-level representatives and corporate officers from both the PBM and Manufacturer Defendants attend these conferences to meet in person and engage in discussions, including those in furtherance of the Insulin Pricing Scheme.

309. In fact, for at least the last eight years, all Manufacturer Defendants have been “Partners,” “Platinum Sponsors,” or “Presidential Sponsors” of these PBM conferences.

310. Notably, many of the forums at these conferences are specifically advertised as offering opportunities for private, non-public communications. For example, as

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<sup>46</sup> The PCMA’s industry funding in the form of “membership dues” is set out in its 2019 Form 990, <https://projects.propublica.org/nonprofits/organizations/383676760/202042969349301134/full> (last visited Jan. 4, 2023).

Presidential Sponsors of these conferences, the Manufacturer Defendants each hosted “private meeting rooms” that offer “excellent opportunities for . . . one-on-one interactions between PBM and pharma executives.”<sup>47</sup>

311. Representatives from each Manufacturer Defendant have routinely met privately with representatives from each PBM Defendant during the Annual Meetings and Business Forum conferences that the PCMA holds (and the manufacturers sponsor) each year.

312. In addition, all PCMA members, affiliates and registered attendees of these conferences are invited to join PCMA-Connect, “an invitation-only LinkedIn Group and online networking community.”<sup>48</sup>

313. As PCMA members, the PBM and Manufacturer Defendants clearly utilized both PCMA-Connect, as well as the private meetings at the PCMA conferences, to exchange information and to reach agreements in furtherance of the Insulin Pricing Scheme.

314. Notably, key at-issue lockstep price increases occurred shortly after the Defendants were together at PCMA meetings. For example, on September 26 and 27, 2017, the PCMA held its annual meeting where each of the Manufacturer Defendants hosted private rooms and executives from each Defendant engaged in several meetings throughout the conference. Mere days after the conference, on October 1, 2017, Sanofi

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<sup>47</sup> PCMA, *The PCMA Annual Meeting 2021 Will Take Place at the Broadmoor in Colorado Springs, CO September 20 and 21*, <https://www.pcmanet.org/pcma-event/annual-meeting-2021/> (an event “tailored specifically for senior executives from PBMs and their affiliated business partners” with “private reception rooms” and “interactions between PBM members, drug manufacturers, and other industry partners”) (last visited Jan. 4, 2023).

<sup>48</sup> PCMA, *PCMA-Connect*, <https://www.pcmanet.org/contact/pcma-connect/> (last visited Sept. 9, 2022).

increased Lantus's list price by 3% and Toujeo's list by 5.4%. Novo Nordisk also recommended that their company make a 4% list price increase effective on January 1, 2018, to match the Sanofi increase.

315. Likewise, on May 30, 2014, Novo Nordisk raised the list price of Levemir several hours after Sanofi made its list price increase on Lantus. This occurred only a few weeks after the 2014 PCMA spring conference in Washington, D.C. attended by representatives from all PBM Defendants.

316. The PBMs control the PCMA and have weaponized it to further their interests and to conceal the Insulin Pricing Scheme. The PCMA has brought numerous lawsuits and lobbying campaigns aimed at blocking drug-pricing transparency efforts, including recently suing the Department of Health and Human Services (HHS) to block the finalized HHS "rebate rule," which would eliminate anti-kickback safe harbors for Manufacturer Payments and instead offer them as direct-to-consumer discounts.

317. Notably, the PCMA's 2019 tax return reports more than a million dollars in revenue for "litigation support." Prior tax returns available at ProPublica show millions of dollars in revenue for "litigation support" (and tens of millions in revenue for "industry relations") year after year.<sup>49</sup>

318. Communications among the PBM Defendants are facilitated by the fluidity and frequency with which executives move from one PBM Defendant to another. For example:

- Mark Thierer worked as an executive at Caremark Rx (now CVS Caremark) prior to becoming the CEO of OptumRx in 2016 (he also served as Chairman of the Board for PCMA starting in 2012);
- Bill Wolfe was the President of the PBM Catalyst Rx (now OptumRx) prior to

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<sup>49</sup> See, e.g., PCMA 2019 Form 990, *supra* note 46, and prior years' returns on ProPublica.



becoming the President of Aetna Rx in 2015 (he also served as a PCMA board member from 2015-2017 while with Aetna Rx);

- Derica Rice, former EVP for CVS Health and President of CVS Caremark previously served as EVP and CFO for Eli Lilly;
- Duane Barnes was the Vice President of Medco (now Express Scripts) before becoming division President of Aetna Rx in 2006 (he also served as a PCMA board member);
- Everett Neville was the division President of Aetna Rx before becoming Senior Vice President of Express Scripts;
- Albert Thigpen was a Senior Vice President at CVS Caremark for eleven years before becoming a senior vice president at OptumRx in 2011;
- Harry Travis was the Chief Operating Officer at Medco (now Express Scripts) before becoming a vice president at Aetna Rx in 2008; he also served as SVP Member Services Operations for CVS Caremark from 2020-2022; and
- Bill Kiefer was a Vice President of Express Scripts for fourteen years before becoming Senior Vice President of Strategy at OptumRx in 2013.

#### **E. The Insulin Pricing Scheme**

319. The market for the at-issue diabetes medications is unique in that it is highly concentrated with no true generics and few biosimilar options. The drugs and biosimilars have similar efficacy and risk profiles.

320. This affords the PBMs great leverage that theoretically could be used in negotiating with the Manufacturer Defendants to drive *down* list prices for the at-issue drugs through open competition.

321. But the PBMs do not want the prices for diabetes medications to go down. A 2022 report by the Community Oncology Alliance put it this way:

Among the different sources of revenue, the most prolific by far is in the form of rebates from pharmaceutical manufacturers that PBMs extract in exchange for placing the manufacturer's product drug on a plan sponsor's formulary or encouraging utilization of the manufacturer's drugs.... [T]he growing number and scale of rebates is the primary fuel of



today's high drug prices. The truth is that PBMs have a vested interest to have drug prices remain high, and to extract rebates off of these higher prices. PBM formularies tend to favor drugs that offer higher rebates over similar drugs with lower net costs and lower rebates.<sup>50</sup>

322. The Manufacturer Defendants understand that PBM Defendants make more money as prices increase. This is confirmed by the Senate Insulin Report after review of internal documents produced by the Manufacturers:

[B]oth Eli Lilly and Novo Nordisk executives, when considering lower list prices, were sensitive to the fact that PBMs largely make their money on rebates and fees that are based on a percentage of a drug's list price.<sup>51</sup>

323. The documents eventually released by the Senate also show how the Manufacturers' pricing strategy focuses on the PBMs' profitability. In an internal August 6, 2015, email, Novo Nordisk executives debated delaying increasing the price of an at-issue drug to make the increase more profitable for CVS Caremark, stating:

Should we take 8/18 [for a price increase], as agreed to by our [pricing committee], or do we recommend pushing back due to the recent CVS concerns on how we take price? . . . We know CVS has stated their disappointment with our price increase strategy (ie taking just after the 45th day) and how it essentially results in a lower price protection, admin fee and rebate payment for that quarter/time after our increase . . . it has been costing CVS a good amount of money.<sup>52</sup>

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<sup>50</sup> Community Oncology Alliance & Frier Levitt, *Pharmacy Benefit Manager Exposé: How PBMs Adversely Impact Cancer Care While Profiting at the Expense of Patients, Providers, Employers, and Taxpayers* (Feb. 2022), [https://communityoncology.org/wp-content/uploads/2022/02/COA\\_FL\\_PBM\\_Expose\\_2-2022.pdf](https://communityoncology.org/wp-content/uploads/2022/02/COA_FL_PBM_Expose_2-2022.pdf) (last visited Jan. 14, 2023).

<sup>51</sup> Grassley & Wyden, *supra* note 4 at 89.

<sup>52</sup> Letter from Raphael A. Prober, Counsel for Novo Nordisk Inc., to Charles E. Grassley & Ron Wyden, S. Fin. Comm. (Mar. 8, 2019), [https://www.finance.senate.gov/imo/media/doc/Novo\\_Redacted.pdf](https://www.finance.senate.gov/imo/media/doc/Novo_Redacted.pdf) (last visited Jan. 15, 2023).

324. The Manufacturer Defendants also understand that because of the PBMs' market dominance, most payors, including in Cleveland, accept the baseline national formularies offered by the PBMs with respect to the at-issue drugs.

325. The Insulin Pricing Scheme was born from these understandings. Both sets of Defendants realized that if the Manufacturers artificially inflate their list prices while paying large, undisclosed Manufacturer Payments back to the PBMs, both the PBMs and Manufacturers would generate billions of unearned dollars. The plan worked.

326. Over the past several years the Manufacturers have raised prices in unison and have paid correspondingly larger Manufacturer Payments to the PBMs.

327. In exchange for the Manufacturers artificially inflating their prices and paying the PBMs substantial amounts in Manufacturer Payments, the PBM Defendants grant the Manufacturer Defendants' diabetes medications elevated prices and preferred status on their national formularies. During the relevant period, the rebate amounts (as a proportion of the list price) grew year-over-year while list prices themselves increased.

328. Beyond increased rebate demands, the PBM Defendants have also sought and received larger and larger administrative fees from the Manufacturers during the relevant period.

329. A recent study by the Pew Charitable Trust estimated that, between 2012 and 2016, the amount of administrative and other fees that the PBMs requested and received from the Manufacturers tripled, reaching more than \$16 billion. The study observed that although rebates were sent to payors during this period, PBMs retained the same volume of rebates in pure dollars, given the overall growth in rebate volume while administrative fees and spread pricing (charging a client payor more for a drug than the PBM pays the pharmacy) further offset reductions in retained rebate volumes.

330. Thus—and contrary to their public representations—the PBM Defendants’ negotiations and agreements with the Manufacturer Defendants (and the formularies that result from these agreements) have caused and continue to cause precipitous price increases for the at-issue drugs.

331. As a result of the Insulin Pricing Scheme, every payor, including Plaintiff, that pays for and/or reimburses for the at-issue drugs has been overcharged.

332. Moreover, the PBMs use this false price to misrepresent the amount of “savings” they generate for diabetics, payors, and the healthcare system. For example, in January 2016, Express Scripts’ president Tim Wentworth stated at the 34th annual JP Morgan Healthcare Conference that Express Scripts “saved our clients more than \$3 billion through the Express Scripts National Preferred Formulary.”<sup>53</sup> Likewise, in April 2019, CVS Caremark president Derica Rice stated, “Over the last three years . . . CVS Caremark has helped our clients save more than \$141 billion by blunting drug price inflation, prioritizing the use of effective, lower-cost drugs and reducing the member’s out-of-pocket spend.”<sup>54</sup>

333. In making these representations, the PBMs fail to disclose that the amount of “savings” they have generated is calculated based on the false list price, which is not paid by any entity in the pharmaceutical pricing chain and which all Defendants are directly responsible for artificially inflating.

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<sup>53</sup> Surabhi Dangi-Garimella, *PBMs Can Help Bend the Cost Curve: Express Scripts’ Tim Wentworth*, AJMC (Jan. 12, 2016), <https://www.ajmc.com/view/pbms-can-help-bend-the-cost-curve-express-scripts-tim-wentworth> (last visited Jan. 15, 2023).

<sup>54</sup> CVS Health, *CVS Health PBM Solutions Blunted the Impact of Drug Price Inflation, Helped Reduce Member Cost, and Improved Medication Adherence in 2018* (Apr. 11, 2019), <https://www.cvshealth.com/news-and-insights/press-releases/cvs-health-pbm-solutions-blunted-the-impact-of-drug-price> (last visited Jan. 11, 2023).

334. The Insulin Pricing Scheme is a coordinated effort between the Manufacturer and PBM Defendants that each agreed to and participated in, and which created enormous profits for all of Defendants. For example:

- a. The Manufacturers and the PBMs are in constant communication and regularly meet and exchange information to construct and refine the PBM formularies that form and fuel the scheme. As part of these communications, the Manufacturers are directly involved in determining not only where their own diabetes medications are placed on the PBMs' formularies and with what restrictions, but also in determining the same for competing products;
- b. The Manufacturers and the PBMs share confidential and proprietary information with each other in furtherance of the Insulin Pricing Scheme, such as market data gleaned from the PBMs' drug utilization tracking efforts and mail-order pharmacy claims, internal medical efficacy studies, and financial data. Defendants then use this information in coordination to set the false prices for the at-issue medications and to construct their formularies in the manner that is most profitable for both sets of Defendants. The data that is used to further this coordinated scheme is compiled, analyzed, and shared either by departments directly housed within the PBM or by subsidiaries of the PBM, as is the case with OptumRx which utilizes OptumInsight and Optum Analytics; and
- c. The Manufacturers and the PBMs engage in coordinated outreach programs directly to patients, pharmacies, and prescribing physicians to convince them to switch to the diabetes medications that are more profitable for the PBMs and Manufacturers, even drafting and editing letters in tandem to send out to diabetes patients on behalf of the PBMs' clients. For example, the Grassley-Wyden committee recently released an email in which Eli Lilly discussed paying Defendant UnitedHealth Group and OptumRx additional rebates for every client that was converted to formularies that exclusively preferred Eli Lilly's at-issue drugs, including Humalog. The email continued: "United's leadership committee made one ask of Lilly – that we are highly engaged in the communication/pull through plan.<sup>55</sup> I of course indicated we fully expect to support this massive patient transition [to Eli Lilly's at-issue drugs favored by United] and provider education with the full breadth of Lilly resources. UHC also proactively thanked Lilly for our responsiveness, solution generation and DBU execution."

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<sup>55</sup> "Pull through" is an industry term that refers to an integrated process between PBMs and Manufacturers aimed at moving market share and increasing sales for a certain product following the PBM granting that product preferred placement on its formulary.

335. Rather than using their prodigious bargaining power to lower drug prices as they claim, Defendants used their dominant positions to work together to generate billions of dollars in illicit profits at the expense of payors like Plaintiff.

**F. Defendants Play Down the Insulin Pricing Scheme and Its Harms**

336. On April 10, 2019, the United States House of Representatives Committee on Energy and Commerce held a hearing on industry practices titled, “Priced Out of a Lifesaving Drug: Getting Answers on the Rising Cost of Insulin.”<sup>56</sup>

337. Representatives from all Defendants testified at the hearing and admitted that the price for insulin had increased exponentially over the past 15 years.

338. Further, each Defendant conceded that the price that diabetics pay out-of-pocket for insulin is too high. For example:

- Dr. Sumit Dutta, SVP and Chief Medical Officer of OptumRx since 2015, stated, “A lack of meaningful competition allows the [M]anufacturers to set high [list] prices and continually increase them which is odd for a drug that is nearly 100 years old and which has seen no significant innovation in decades. These price increases have a real impact on consumers in the form of higher out-of-pocket costs.”
- Thomas Moriarty, General Counsel for CVS admitted “[a] real barrier in our country to achieving good health is cost, including the price of insulin products which are too expensive for too many Americans. Over the last several years, prices for insulin have increased nearly 50 percent. And over the last ten years, [list] price of one product, Lantus, rose by 184 percent.”
- Mike Mason, Senior Vice President of Eli Lilly when discussing how much diabetics pay out-of-pocket for insulin stated “it’s difficult for me to hear anyone in the diabetes community worry about the cost of insulin. Too many people today don’t have affordable access to chronic medications . . .”
- Kathleen Tregoning, Executive Vice President External Affairs at Sanofi, testified, “Patients are rightfully angry about rising out-of-pocket costs and we all have a responsibility to address a system that is clearly failing too many

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<sup>56</sup> <https://www.congress.gov/event/116th-congress/house-event/109299?s=1&r=3> (last visited Jan. 9, 2023) (hereinafter *Priced Out of a Lifesaving Drug*).

people. . . we recognize the need to address the very real challenges of affordability . . . Since 2012, average out-of-pocket costs for Lantus have risen approximately 60 percent for patients . . .”

- Doug Langa, Executive Vice President of Novo Nordisk, stated, “On the issue of affordability . . . I will tell you that at Novo Nordisk we are accountable for the [list] prices of our medicines. We also know that [list] price matters to many, particularly those in high-deductible health plans and those that are uninsured.”

339. Notably, none of the testifying Defendants claimed that the significant increase in the price of insulin was related to competitive factors such as increased production costs or improved clinical benefit.

340. Instead, Novo Nordisk’s President Doug Langa’s written testimony for the April 2019 hearing recognized “misaligned incentives” that have led to higher drug costs, including for insulin: “Chief among these misaligned incentives is the fact that the rebates pharmaceutical companies pay to PBMs are calculated as a percentage of WAC [list] price. That means a pharmaceutical company fighting to remain on formulary is constrained from lowering WAC price, or even keeping the price constant, if a competitor takes an increase. This is because PBMs will then earn less in rebates and potentially choose to place a competitor’s higher-priced product on their formulary to the exclusion of others.” Likewise, Mr. Langa’s responses to questions for the record conceded that “[t]he disadvantage of a system in which administrative fees are paid as a percentage of the list price is that there is increased pressure to keep list prices high. . . .” The hearing transcript records Mr. Langa’s further comments in this regard:

[T]here is this perverse incentive and misaligned incentives and this encouragement to keep list prices high. And *we’ve been participating in that system* because the higher the list price, the higher the rebate . . . There is a significant demand for rebates.... *We’re spending almost \$18 billion a year in rebates, discount, and fees, and we have people with insurance with diabetes that don’t get the benefit of that.* (emphasis added)

341. Eli Lilly admitted that it raises list prices as a quid pro quo for formulary positions. At the April 2019 Congressional hearing, Mike Mason, Senior Vice President of Eli Lilly testified:

Seventy-five percent of our list price is paid for rebates and discounts . . . . \$210 of a vial of Humalog is paid for discounts and rebates. . . . We have to provide rebates [to PBMs] in order to provide and compete for that [formulary position] so that people can use our insulin.

In the very next question, Mr. Langa of Novo Nordisk was asked, “[H]ave you ever lowered a list price? His answer, “We have not.”

342. Sanofi’s Executive Vice President for External Affairs, Kathleen Tregoning, testified:

The rebates is [sic] how the system has evolved. . . . I think the system became complex and rebates generated through negotiations with PBMs are being used to finance other parts of the healthcare system and not to lower prices to the patient.

Her written response to questions for the record acknowledged that “it is clear that payments based on a percentage of list price result in a higher margin [for PBMs] for the higher list price product than for the lower list price product.”

343. The PBM Defendants also conceded at the April 2019 Congressional hearing that they grant preferred, or even exclusive, formulary position because of higher Manufacturer Payments paid by the Manufacturer Defendants.

344. In her responses to questions for the record, Amy Bricker—former President of Express Scripts, a former PCMA board member, and now an executive at CVS Health—confirmed that “manufacturers lowering their list prices” would give patients “greater access to medications;” yet when asked to explain why Express Scripts did not grant an insulin with a lower list price preferred formulary status, answered, “Manufacturers do



give higher discounts [i.e., payments] for exclusive [formulary] position . . .” When asked why the PBM would not include both costly and lower-priced insulin medications on its formulary, Ms. Bricker stated plainly, “We’ll receive less discount in the event we do that.”<sup>57</sup>

345. As Dr. Dutta, SVP of OptumRx, perversely reasoned, the cheaper list-priced alternative Admelog is not given preference on the formulary because “it would cost the payer more money to do that . . . [b]ecause the list price is not what the payer is paying. They are paying the net price.”<sup>58</sup> In other words, under the pricing scheme, PBMs and manufacturers can make a drug with a lower list price effectively more expensive for payors and then ostensibly save payors from that artificially-inflated price by giving preference to drugs that had higher list prices to begin with (yielding higher Manufacturer Payments to the PBMs).

346. While all Defendants acknowledged before Congress their participation in conduct integral to the Insulin Pricing Scheme, none revealed its inner workings or the connection between their coordination and the economic harm that payors, like Plaintiff, and Beneficiaries were unwittingly suffering. Instead, in an effort to obscure the true reason for precipitous price increases, each Defendant group pointed the finger at the other as the more responsible party.

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<sup>57</sup> Buried in Express Scripts’ 2017 10-K is the following: “We maintain contractual relationships with numerous pharmaceutical manufacturers, which provide us with, among other things administrative fees for managing rebate programs, including the development and maintenance of formularies that include particular manufacturer’s products . . . .” That is, the Manufacturers pay the PBMs to effectively participate in the creation of formularies that payors are required to adopt as a condition for obtaining PBM services. Express Scripts Annual Report (Form 10-K) (FYE Dec. 31, 2017) at 24. It also notes that its business would be “adversely affected” if it were to “lose [its] relationship with one or more key pharmaceutical manufacturers.” *Id.*

<sup>58</sup> *Id.* As noted in the hearing, even the “cheaper” alternative Admelog “costs over \$200 a bottle.”



347. The PBM Defendants testified to Congress that the Manufacturer Defendants are solely responsible for their list price increases and that the Manufacturer Payments that the PBMs receive are not correlated to rising insulin prices.

348. To the contrary, the amount the Manufacturers kick back to the PBM Defendants is directly correlated to an increase in list prices—on average, a \$1 increase in Manufacturer Payments is associated with a \$1.17 increase in list price. Reducing or eliminating Manufacturer Payments would lower prices and reduce out-of-pocket expenditures.

349. Further, in large part because of the increased list prices and related Manufacturer Payments, the PBMs' profit per prescription has grown substantially over the same period that insulin prices have steadily increased. For example, since 2003 Defendant Express Scripts has seen its profit per prescription increase more than 500% per adjusted prescription.<sup>59</sup>

350. Novo Nordisk's President Doug Langa submitted written testimony to Congress acknowledging "there is no doubt that the WAC [list price] is a significant component" of "what patients ultimately pay at the pharmacy counter." Yet, the Manufacturers urged upon Congress the fiction that the PBMs were solely to blame for insulin prices because of their demands for rebates in exchange for formulary placement. The Manufacturers claimed their hands were tied and sought to conceal their misconduct by suggesting that they have not profited from rising insulin prices.

351. Given the Manufacturers' claims that rebates were the sole reason for rising

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<sup>59</sup> David Balto, *How PBMs Make the Drug Price Problem Worse*, Hill (Aug. 31, 2016, 5:51 PM), <https://thehill.com/blogs/pundits-blog/healthcare/294025-how-pbms-make-the-drug-price-problem-worse> (last visited Jan. 15, 2023).

prices, each was asked directly during the Congressional hearing to guarantee it would decrease list prices if rebates were restricted or eliminated. The spokespersons for Eli Lilly, Novo Nordisk, and Sanofi all said only that they would “consider it.”

352. In addition, a 2020 study from the Institute of New Economic Thinking titled, “Profits, Innovation and Financialization in the Insulin Industry,” demonstrates that during the time insulin price increases were at their steepest, distributions to the Manufacturers’ shareholders in the form of cash dividends and share repurchases totaled \$122 billion. In fact, during this time, the Manufacturers spent a significantly lower proportion of profits on R&D compared to shareholder payouts. The paper also notes that “[t]he mean price paid by patients for insulin in the United States almost tripled between 2002 and 2013” and that “per-person spending on insulin by patients and insurance plans in the United States doubled between 2012 and 2016, despite only a marginal increase in insulin use.”<sup>60</sup>

353. The 2022 Community Oncology Alliance report found:<sup>61</sup>

[T]here are several important ways that PBM rebates increase the costs of drugs for both plan sponsors and patients. . . . PBMs employ exceedingly vague and ambiguous contractual terms to recast monies received from manufacturers outside the traditional definition of rebates, which in most cases must be shared with plan sponsors. Rebate administration fees, *bona fide* service fees, and specialty pharmacy discounts/fees are all forms of money received by PBMs and rebate aggregators which may not be shared with (or even disclosed to) the plan sponsor. These charges serve to increase the overall costs of drugs, while providing no benefit whatsoever to plan sponsors. . . . The total drug spend of a plan sponsor, regardless of whether it is a federal or state governmental

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<sup>60</sup> Rosie Collington, *Profits, Innovation and Financialization in the Insulin Industry*, Inst. For New Econ. Thinking (Apr. 2020), <https://www.ineteconomics.org/research/research-papers/profits-innovation-and-financialization-in-the-insulin-industry> (last visited Jan. 15, 2023).

<sup>61</sup> Community Oncology Alliance, *supra* note 50.

program or a self-funded employer, will inevitably increase because PBMs are incentivized to favor expensive drugs that yield high rebates. . . .

354. In January 2021, the Senate Finance Committee (Grassley-Wyden) issued a report titled “Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug”<sup>62</sup> that detailed Congress’s findings after reviewing more than 100,000 pages of internal company documents from Sanofi, Novo Nordisk, Eli Lilly, CVS Caremark, Express Scripts, OptumRx, and Cigna. The report concluded, among other things:

- The Manufacturer Defendants retain more revenue from insulin than in the 2000s—for example, Eli Lilly has reported a steady increase in Humalog revenue for more than a decade—from \$1.5 billion in 2007 to \$3 billion in 2018;
- The Manufacturer Defendants have aggressively raised the list price of their insulin products absent significant advances in the efficacy of the drugs; and
- The Manufacturer Defendants only spend a fraction of their revenue related to the at-issue drugs on research and development—Eli Lilly spent \$395 million on R&D costs for Humalog, Humulin, and Basaglar between 2014-2018 during which time the company generated \$22.4 billion in revenue on these drugs.

355. In fact, despite their finger-pointing before Congress, both the Manufacturers and PBMs are responsible for their concerted efforts to create the Insulin Pricing Scheme.

#### **G. All Defendants Profit from the Insulin Pricing Scheme**

356. Under the Insulin Pricing Scheme, the Manufacturer Defendants pay the PBM Defendants opaque but significant Manufacturer Payments in exchange for formulary placement, which garners the Manufacturers greater revenues and steady profit margins. The PBM Defendants grant national formulary position to at-issue drugs in exchange for large Manufacturer Payments generated by inflated drug prices.

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<sup>62</sup> Grassley & Wyden, *supra* note 4 at 5, 7.

357. Inflated prices also to earn the Manufacturers hundreds of millions of dollars in tax breaks by basing their deductions for donated insulins on the inflated list prices.

358. Because of the increased list prices, and related Manufacturer Payments, the PBMs' profit per prescription has grown exponentially during the relevant period as well. A recent study published in the Journal of the American Medical Association concluded that the amount of money that goes to the PBM Defendants for each insulin prescription increased more than 150% from 2014 to 2018. In fact, for transactions in which the PBM Defendants control the PBM and the pharmacy (e.g., Caremark-CVS pharmacy), these Defendants were capturing an astonishing 40% of the money spent on each insulin prescription (up from only 25% just four years earlier), even though they do not contribute to the development, manufacture, innovation, or production of the product.<sup>63</sup>

359. The PBM Defendants profit from the artificially inflated prices created by the Insulin Pricing Scheme in several ways, including: (1) retaining a significant, yet undisclosed, percentage of the Manufacturers Payments, (2) using the inflated list price to generate profits from pharmacies, and (3) relying on the inflated list price to drive up the PBMs' margins through their own mail-order pharmacies.

*The PBMs Pocket a Substantial Share of the Manufacturers' Secret Payments*

360. The first way in which the PBMs profit from the Insulin Pricing Scheme is by keeping a significant portion of the secret Manufacturer Payments.

361. The amount that the Manufacturers pay back to the PBMs has increased over time both in real dollars and as a proportion of the ever-increasing list prices.

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<sup>63</sup> Karen Van Nuys, *et al.*, *Estimation of the Share of Net Expenditures on Insulin Captured by US Manufacturers, Wholesalers, Pharmacy Benefit Managers, Pharmacies, and Health Plans From 2014 to 2018*, JAMA Network (Nov. 5, 2021), <https://jamanetwork.com/journals/jama-health-forum/fullarticle/2785932> (last visited Jan. 15, 2023).

362. Historically, contracts between PBMs and payors allowed the PBMs to keep most or all rebates they received, rather than forwarding them to the payor.

363. Over time, payors secured contract provisions guaranteeing payment to them of all or some portion of the rebates paid by the Manufacturers to the PBMs. Critically, however, “rebates” are only one aspect of the total secret Manufacturer Payments, particularly as “rebates” are narrowly defined and qualified by vague exceptions in the PBM Defendants’ contracts with payors.

364. Indeed, as described in the Senate Insulin Report, the PBMs and Manufacturers coordinate to determine the contract options made available to payors: “Contracts between PBMs and manufacturers provide a menu of options from which their health plan clients can choose certain terms and conditions.”<sup>64</sup> The contracts between the PBMs and Manufacturers also “stipulate terms the plans must follow regarding factors such as formulary placement and competition from other drugs in the therapeutic class.”<sup>65</sup> Thus, the Manufacturers ultimately played a role in dictating the terms and conditions of the contracts that payors like Plaintiff entered into with PBMs. Of course, the payors were not involved in the coordination or the negotiation of the contracts between the PBMs and Manufacturers, and the PBMs disclosed only the fact that such relationships may exist. But the terms of the contracts, the consideration exchanged between the PBMs and Manufacturers, and the means of reaching these determinations all were—and remain—shrouded in secrecy.

365. The PBM and Manufacturer Defendants thus created a “hide-the-ball”

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<sup>64</sup> Grassley & Wyden, *supra* note 4 at 40.

<sup>65</sup> *Id.* at 44.

system where payors like Plaintiff are not privy to rebate negotiations or contracts between the Manufacturers and the PBMs. The consideration exchanged between them (and not shared with payors) is continually labeled and relabeled. As more payors moved to contracts that required PBMs to remit some or all of the manufacturer “rebates” through to the payor, the PBMs rechristened Manufacturer Payments to shield them from scrutiny and from their payment obligations. Payments once called “rebates” now were termed “administrative fees,” “volume discounts,” “service fees,” “inflation fees,” or other industry monikers designed to obfuscate the substantial sums being secretly exchanged between the PBM Defendants and the Manufacturers.

366. The Senate Commerce, Science and Transportation Committee recently released testimony from David Balto—a former antitrust attorney with the DOJ and Policy Director for the FTC’s Bureau of Competition—from a hearing on fairness and transparency in drug pricing:

The PBM rebate system turns competition on its head with PBMs seeking higher, not lower prices to maximize rebates and profits. In the past decade, PBM profits have increased to \$28 billion annually.. . . PBMs establish tremendous roadblocks to prevent payors from knowing the amount of rebates they secure. Even sophisticated buyers are unable to secure specific drug by drug rebate information. PBMs prevent payors from being able to audit rebate information. As the Council of Economic Advisors observed, the PBM market lacks transparency as “[t]he size of manufacturer rebates and the percentage of the rebate passed on to health plans and patients are secret.” Without adequate transparency, plan sponsors cannot determine if the PBMs are fully passing on any savings, or whether their formulary choices really benefit the plan and subscribers.

367. The renamed, undisclosed Manufacturer Payments are substantial. “Administrative fees” are one example. A heavily redacted complaint filed by Defendant

Express Scripts in 2017 revealed that Express Scripts retains up to thirteen times more in “administrative fees” than it remits to payors in rebates.<sup>66</sup>

368. These so-called administrative fees typically are based on a percentage of the drug price—as opposed to a flat fee—such that even if the actual “administrative” cost associated with processing two drugs is the same, the “administrative fee” would be correspondingly higher for the higher-priced drug, which again creates (by design) a perverse incentive to give preference to more expensive drugs. Moreover, the PBM Defendants’ contracts with payors narrowly define “rebates” by tying them to patient drug utilization. Thus, rebates for formulary placement (which are not tied to patient drug utilization) are characterized as “administrative fees” that are not remitted to payors. Such payments are beyond a payor’s contractual audit rights because those rights are limited to “rebate” payments and these “administrative fees” have been carved out from the definition of “rebates.”

369. The opaque nature of these arrangements between the Manufacturers and PBM Defendants also makes it impossible for a given payor to discover, much less assess or confront, conflicts of interest that may affect it or its members. The Senate Insulin Report observed with respect to these arrangements: “Relatively little is publicly known about these financial relationships and the impact they have on insulin costs borne by consumers.”<sup>67</sup>

370. Not surprisingly, the PBMs have gone to great lengths to obscure these renamed Manufacturer Payments to avoid scrutiny from payors and others.

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<sup>66</sup> *Express Scripts, Inc. v. Kaleo, Inc.*, No. 4:17-cv-01520-RLW (E.D. Mo. 2017). Balto, *supra* note 59.

<sup>67</sup> Grassley & Wyden, *supra* note 4 at 4.

371. For example, as to the Manufacturer Payments now known as “inflation fees,” the PBMs often create a hidden gap between how much the Manufacturers pay them to increase their prices and the amount in “price protection guarantees” that the PBMs agree to pay back to their client payors.

372. In particular, the Manufacturer Defendants often pay the PBM Defendants “inflation fees” to increase the price of their diabetes medications. The thresholds for these payments are typically set at around 6% to 8%—if the Manufacturer Defendants raise their prices by more than the set percentage during a specified period, they pay the PBM Defendants an additional “inflation fee” (based on a percentage of the list prices).

373. For many of their clients, the PBMs have separate “price protection guarantees” providing that if the overall drug prices for that payor increase by more than a set amount, then the PBMs will remit a portion of the amount to the client.

374. The PBMs set these “price protection guarantees” at a higher rate than the thresholds that trigger the Manufacturers’ “inflation fees,” usually around 10%-15%.

375. Thus, if the Manufacturers increase their list prices more than the 6% (or 8%) inflation fee rate, but less than the 10%-15% client price protection guarantee rate, then the PBMs keep all of these “inflation fee” payments. This is a win-win for the Manufacturers and PBM Defendants—they share and retain the entire benefit of these price increases while the PBM contracts with payors imply that payors are protected from price hikes by their price protection guarantees.

376. The PBM Defendants also hide the renamed Manufacturer Payments with “rebate aggregators.” Rebate aggregators, sometimes referred to as rebate group purchasing organizations (“GPOs”), are entities that negotiate for and collect payments from drug manufacturers, including the Manufacturer Defendants, on behalf of a large



group of pharmacy benefit managers (including the PBM Defendants) and different entities that contract for pharmaceutical drugs.

377. These rebate aggregators are often affiliated with or owned by the PBM Defendants, such as Ascent Health Services (Express Scripts), Coalition for Advanced Pharmacy Services and Emisar Pharma Services (OptumRx), and Zinc (CVS Caremark).

378. The PBM Defendants carefully guard the revenue streams from their rebate aggregator activities, concealing them through complex contractual relationships and not reporting them separately in their quarterly SEC filings.

379. Certain rebate-aggregator companies are located offshore, including, for example, in Switzerland (Express Scripts' Ascent Health) and Ireland (Emisar Pharma Services), thereby precluding adequate oversight.

380. As summarized by the recent Community Oncology Alliance report:<sup>68</sup>

PBMs have increasingly “delegated” the collection of manufacturer rebates to “rebate aggregators,” which are often owned by or affiliated with the PBMs, without seeking authorization from plan sponsors and without telling plan sponsors. . . . Even some of the major PBMs (i.e., the “Big Three” PBMs) sometimes find themselves contracting with other PBMs’ rebate aggregators for the collection of manufacturer rebates. . . . In both the private sector and with respect to government health care programs, the contracts regarding manufacturer rebates (i.e., contracts between PBMs and rebate aggregators, as well as contracts between PBMs/rebate aggregators and pharmaceutical manufacturers) are not readily available to plan sponsors.

381. For example, a 2017 audit conducted by a local governmental entity on Defendant OptumRx related to its PBM activities from 2013 to 2015 concluded that the auditor was unable to verify the percentage of rebates OptumRx remitted to its client

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<sup>68</sup> Community Oncology Alliance, *supra* note 50.

payor because OptumRx would not allow the auditor access to its rebate contracts. The audit report explained:

Optum[Rx] has stated that it engaged the services of an aggregator to manage its rebate activity. Optum[Rx] shared that under this model, they are paid by their aggregator a certain amount per prescription referred. Then, the aggregator, through another entity, seeks rebates from the drug manufacturers, based upon the referred [Payor Client] prescription utilization, and retains any rebate amounts that may be received. Optum[Rx] states that they have paid [Payor Client] all amounts it has received from its aggregator, and that they do not have access to the contracts between the aggregator (and its contractors) and the manufacturer. However, our understanding is that Optum[Rx] has an affiliate relationship with its aggregator.<sup>69</sup>

382. A footnote in the audit report clarifies that “Optum[Rx] contracted with Coalition for Advanced Pharmacy Services (CAPS), and CAPS in turn contracted with Express Scripts, Inc.”

383. In other words, according to this report, OptumRx contracts with its own affiliate aggregator Coalition for Advanced Pharmacy Services, who then contracts with OptumRx’s co-conspirator Express Scripts, who then contracts with the Manufacturers for rebates related to OptumRx’s client’s drug utilization. OptumRx then uses this complex relationship to obscure the amount of Manufacturer Payments that are being generated from its client’s utilization.

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<sup>69</sup> Laura Rogers & Stacey Thomas, Broward County Florida, Audit of Pharmacy Benefit Management Services Agreement, No. 18-13 (Dec. 7, 2017), [https://www.broward.org/Auditor/Reports/Documents/2017\\_1212%20Agenda%20Review%20of%20Pharmacy%20Benefit%20Management%20Services%20by%20StoneBridge/2017\\_1212%20Exh1\\_OptumRx.pdf](https://www.broward.org/Auditor/Reports/Documents/2017_1212%20Agenda%20Review%20of%20Pharmacy%20Benefit%20Management%20Services%20by%20StoneBridge/2017_1212%20Exh1_OptumRx.pdf) (last visited Jan. 15, 2023).

384. A subsequent audit by the same local entity—covering the period September 2017 to September 2018, concluded:<sup>70</sup>

Several material weaknesses in Broward’s agreement with Optum were identified, many of which are commonplace across pharmacy benefit manager agreements in general. Due to contract weaknesses, a comparison of Broward’s PBM agreement, including rebate amounts received, to the Consultant’s marketplace data is not feasible. Broward could save an estimated \$1,480,000 per year in net prescription drug benefit expenses (based upon minimum rebate guarantees) by switching from its current flawed agreement with Optum, to an agreement with its Coalition, which offers clearly defined terms, increased rebate guarantees and cost saving requirements.

Among other “loopholes” discovered in the contract were a number of “flawed” (i.e., vague and manipulable) definitions—including the definition of “Rebates,” which “allows the exclusion of monies that should be included—and limitation with respect to “Pass Through Transparency Pricing.”

385. The January 2021 Grassley-Wyden Senate Report summarizing findings of their two-year probe into the Insulin Pricing Scheme contained the following observation on these rebate aggregators:<sup>71</sup>

[T]he recent partnership between Express Scripts and Prime Therapeutics may serve as a vehicle to avoid increasing legislative and regulatory scrutiny related to administrative fees by channeling such fees through a Swiss-based group purchasing organization (GPO), Ascent Health. While there are several regulatory and legislative efforts underway to prohibit manufacturers from paying administrative fees to PBMs, there is no such effort to change the GPO safe harbor rules. New arrangements used by PBMs to collect fees should be an area of continued investigative interest for Congress.

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<sup>70</sup> Broward County, Florida, *Analysis of Broward County’s Prescription Drug Coverage*, [https://www.broward.org/Auditor/Reports/Reports/082019\\_Exh1\\_BCRxDrug\\_19-15.pdf](https://www.broward.org/Auditor/Reports/Reports/082019_Exh1_BCRxDrug_19-15.pdf) (last visited Jan. 10, 2023).

<sup>71</sup> Grassley & Wyden, *supra* note 4 at 83.

386. Federal regulations governing Medicare attempt to capture all possible forms of Direct or Indirect Remuneration (DIR) to PBMs (and plan sponsors), defining it as “any form of price concession” received by a plan sponsor or PBM “from any source,” including “discounts, chargebacks, rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, legal judgment amounts, settlement amounts from lawsuits or other legal action, and other price concessions or similar benefits. DIR also includes price concessions from and additional contingent payments to network pharmacies that cannot reasonably be determined at the point of sale.”<sup>72</sup> The Department of Health and Human Services, Centers for Medicare & Medicaid Services (CMS) considers all of the following as DIR: rebates, grants, reduced price administrative services, PBM-retained rebates, PBM rebate guarantee amounts, all post-point of sale payments by pharmacies that are not included in the negotiating price including dispensing incentive payments, prompt pay discounts, and payment adjustments. On the other hand, “bona fide service fees from pharmaceutical manufacturers” and “remuneration for administrative services with no impact on the sponsor’s or PBM’s drug cost (e.g., PBM incentive payments)” are *not* considered DIR *but only to the extent they reflect fair market value for services rendered*.<sup>73</sup>

387. Because the PBMs are able to retain and conceal a majority of the secret Manufacturer Payments that they receive, they are able to make significant profits on the Insulin Pricing Scheme.

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<sup>72</sup> CMS, *Final Medicare Part D DIR Reporting Guidance for 2021* at 7, <https://www.cms.gov/files/document/final2021dirreportingreqsmemo508v3.pdf> (last visited Jan. 15, 2023).

<sup>73</sup> *Id.* at 6-7.

388. Even when payor clients receive a portion of the Manufacturer Payments from their PBM, the payors are significantly overcharged, given the extent to which Defendants have deceptively and egregiously inflated the prices of the at-issue drugs.

*The Insulin Pricing Scheme Allows the PBMs to Profit Off Pharmacies*

389. A second way the PBM Defendants profit off the Insulin Pricing Scheme is by using the Manufacturers' inflated price to derive profit from the pharmacies with whom they contract, including those in Cleveland.

390. Each PBM Defendant decides which pharmacies are included in the PBM's network and how much it will reimburse these pharmacies for each drug dispensed.

391. The PBMs pocket the spread between the amount that the PBMs are paid by their clients for the at-issue drugs (which are based on the prices generated by the Insulin Pricing Scheme) and the amount the PBM reimburses the pharmacy (which often is less). In other words, the PBMs charge a client like Plaintiff more for a drug than the PBM pays the pharmacy and pockets the difference.

392. A bipartisan bill introduced in the Senate in 2022 (the Pharmacy Benefit Manager Transparency Act—S. 4293)—would have, criminalized spread pricing, which the bill defined as “[c]harg[ing] a health plan or payer a different amount for a prescription drug’s ingredient cost or dispensing fee than the amount the pharmacy benefit manager reimburses a pharmacy for the prescription drug’s ingredient cost or dispensing fee where the pharmacy benefit manager retains the amount of any such difference.” The bill has not yet been enacted.<sup>74</sup>

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<sup>74</sup> <https://www.govtrack.us/congress/bills/117/s4293> (last visited Jan. 10, 2023). A new PBM Transparency Act (S.127) was introduced in January 26, 2023.

393. The PBMs' industry-funded trade association PCMA, spent \$7.8 million on federal lobbying in 2021 and more \$6 million through the third quarter of 2022.<sup>75</sup>

394. The PBMs often disclose the concept of spread pricing to payors, but only in vague terms that require no accountability and are not subject to the payors' audit rights because the revenue is not defined as a "rebate" in PBM contracts with payors.

395. This spread pricing, like the secret Manufacturer Payment negotiation, happens behind closed doors. There is no transparency, no commitment from the PBM Defendants to take into account the cost effectiveness of a drug, and no communication to either the payor or the pharmacy to let them know if they are getting a fair deal.

396. The higher the Manufacturers' list prices, the more money the PBMs make off this spread. At the same time, a Beneficiary's out-of-pocket co-pay or deductible cost often is more than if the client had simply paid cash outside of his or her plan. On top of this, the PBM contracts generally allow no rebates to payors where the Beneficiary is responsible for 100% of the drug cost, e.g., under his or her deductible.

397. The PBM Defendants also use the Insulin Pricing Scheme to profit from pharmacies by charging the pharmacies post-purchase fees, including DIR (Direct or Indirect Remuneration) fees, based on the list prices—and again, the higher the list price for each diabetes medication sold, the more fees the PBMs generate. They also apply "retrospective" discounts so, for example, a payor's (and member's co-pay or deductible) cost may be \$100, but the price may be discounted post-purchase between the PBM and the (often self-owned) pharmacy to \$90, with the spread going to the PBM.

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<sup>75</sup> <https://www.opensecrets.org/federal-lobbying/clients/summary?cycle=2021&id=D000028342> (2021); <https://www.opensecrets.org/federal-lobbying/clients/summary?cycle=2022&id=D000028342> (2022) (last visited Jan. 10, 2023).

398. CMS addressed these and similar DIR issues in a proposed rule in 2017. While noting the growth of “pharmacy price concessions” that “are negotiated between pharmacies and their sponsors or PBMs,” CMS nevertheless concluded:<sup>76</sup>

When manufacturer rebates and pharmacy price concessions are not reflected in the price of a drug at the point of sale, beneficiaries might see lower premiums, but they do not benefit through a reduction in the amount they must pay in cost-sharing, and thus, end up paying a larger share of the actual cost of a drug. Moreover, given the increase in manufacturer rebates and pharmacy price concessions in recent years, the point-of-sale price of a drug that a Part D sponsor reports on a PDE record as the negotiated price is rendered less transparent . . . .

CMS expressed further concern that when rebates and other price concessions are not reflected in the negotiated point-of-sale drug price, it “can impede beneficiary access to necessary medications, which leads to poorer health outcomes and higher medical care costs for beneficiaries . . . .”

399. PBM Defendants thus make money “coming and going.” In a pre-PBM world, a competitively priced drug might have a (hypothetical) net cost to a health plan of \$50, which it paid. PBMs enter the picture and collude with Manufacturers to increase the list price to \$150. The PBMs then “negotiate” the inflated price down to \$100 and take a \$50 rebate, some of which may be forwarded to the payor, whose net cost is less than the inflated list price, but whose real-world cost is considerably more than if a PBM was not involved. The PBM also receives “administrative fees” for including certain drugs on its formularies. The PBM also receives “service fees” or other payment for “administrative services” provided to the Manufacturers such as “formulary compliance initiatives,”

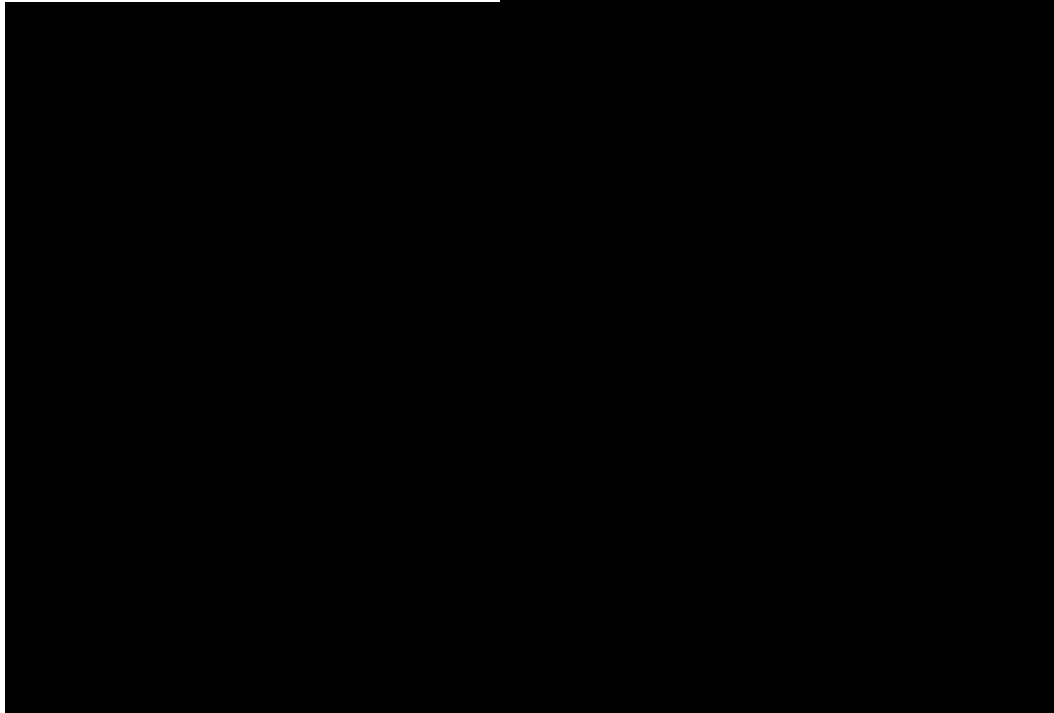
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<sup>76</sup> Medicare Program; Contract Year 2019 Policy and Technical Changes, 82 Fed. Reg. 56336 (Nov. 29, 2017), <https://www.govinfo.gov/content/pkg/FR-2017-11-28/pdf/2017-25068.pdf>.

“education services,” or the sale of non-patient claim information. These revenue streams are outside the definition of “rebates.” The PBM then charges payors administrative fees for providing pharmacy benefit management services and charges drug costs (aka ingredient costs) and per-prescription dispensing fees, as well as additional administrative fees for services not included in the PBM’s general administrative obligations. The PBM receives rebates and/or discounts (pre-purchase or post-purchase) from the pharmacies, which the PBM often owns. These too are excluded from the definition of “rebates.” These and other vaguely described revenue streams are sometimes disclosed, but only in hazy, general terms. And they are beyond a payor’s contractual rights to audit for “transparency” purposes because they are not defined “rebates.” Additionally, the PBM retains all interest on, and the time-value of, the rebates pending payment.

400. This is one example of a PBM “disclosure” excerpted from Plaintiff’s 2012 PBM contract with CVS Caremark:

Disclosure of Manufacturer Fees.



(Emphasis added.)



Payors have no access to, and no knowledge of, the intricacies of the dealings between the PBM Defendants and the Manufacturers that are shrouded by such vague “disclosures” (which vary in detail, but not in substance, in all three of the PBM Defendants’ adhesive contracts). These disclosures could be summed up in a single sentence: “We pass along ‘rebates’ to client payors, except when we don’t.”

*The Insulin Pricing Scheme Increases PBM Mail-Order Profits*

401. Another way PBM Defendants profit from the Insulin Pricing Scheme is through their mail-order pharmacies. The higher the price that PBM Defendants can get customers, such as Plaintiff, to pay for diabetes medications, the higher the profits PBM Defendants realize through their mail-order pharmacies.

402. Because the PBMs base the price they charge for the at-issue diabetes medications on the Manufacturers’ price, the more the Manufacturers inflate their prices, the more money the PBMs make. For example, the PBMs have colluded with the Manufacturers so that the PBMs often know when the Manufacturers are going to raise their prices. The PBMs use this opportunity to purchase a significant amount of the at-issue drugs prior to the price increase, at the lower rate. Then, after the Manufacturers raise their price, the PBMs charge their mail-order customers based on the higher, increased prices and pocket the difference. The PBMs make significant amounts of money on this arbitrage scheme.

403. The PBM Defendants also charge the Manufacturer Defendants fees related to their mail-order pharmacies, such as pharmacy supplemental discount fees, that are directly tied to the Manufacturers’ price. Once again, the higher the price is, the more money the PBMs make on these fees.

404. In sum, every way in which the PBMs make money on diabetes medications

is tied directly to creating higher prices and inducing larger secret Manufacturer Payments. The PBMs are not lowering the price of diabetes medications as they publicly represent—they are making billions of dollars by fueling these skyrocketing prices.

**H. Plaintiff Purchased At-Issue Drugs Directly from Defendant CVS Caremark**

405. As a government employer, Plaintiff serves its residents by providing public safety, emergency management, and health services, just to name a few of its vital roles. As more federal and state responsibilities are passed on to local government, Plaintiff has a growing list of obligations with a limited budget. Consequently, any significant increase in spending can have a severe detrimental effect on Plaintiff's overall budget and, in turn, negatively impact its ability to provide essential services to the community.

406. One of the benefits Plaintiff provides its Beneficiaries is paying for a large portion of their pharmaceutical purchases. In this role, Plaintiff spent significant amounts on the at-issue diabetes medications during the relevant period. Because Plaintiff maintains a self-funded plan, it does not rely on a third-party insurer to pay for its insured's medical care, pharmaceutical benefits, or prescription drugs. Rather, Plaintiff directly contracts with, and directly pays, PBMs (and their affiliated pharmacies) for pharmaceutical benefits and prescription drugs, including the at-issue medications.

407. Plaintiff is the only named party that pays the full purchase price for the at-issue drugs, and the only named party that has not knowingly participated in the Insulin Pricing Scheme. Neither the PBMs nor the Manufacturers suffer losses from the Insulin Pricing Scheme. As part of purchasing the at-issue drugs from the PBMs, Plaintiff directly pays the PBMs artificially inflated costs resulting from the Insulin Pricing Scheme, including "administrative fees," "inflation fees," "discounts," and more. Because the

Defendants control the market for these life-saving drugs, Plaintiff has no choice but to pay these exorbitant, artificially inflated prices directly to the PBM Defendants.

408. Diabetes medications have consistently been a significant financial expense for Plaintiff. For example, a 2017 Prescription Benefit Review conducted by Plaintiff's PBM, CVS Caremark, noted that its most significant prescription expense by therapeutic class was for antidiabetic drugs, with more than \$2,000,000 being spent by Plaintiff on this class of drugs in 2017 alone. By comparison, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED].

409. In 2017, among the twenty-five top drugs by expense for Plaintiff, four were at-issue diabetes medications in this case: Victoza, Novolog Flexpen, Novolog, and Basaglar Kwikpen.

410. CVS Caremark's 2019 Annual review noted that [REDACTED]

[REDACTED]

[REDACTED]. By comparison, [REDACTED]

[REDACTED]

[REDACTED].

411. In 2019, among the top twenty-five drugs by expense for Plaintiff, three were at-issue diabetes medications: Trulicity (fourth most costly drug to Plaintiff in 2019), Victoza, and Novolog.

412. To administer its health plans' pharmaceutical program, Plaintiff relies on the CVS Caremark as its administrative agent, for the supposed purposes of limiting its administrative burden and controlling pharmaceutical drugs costs.

413. Plaintiff has relied on Defendant CVS Caremark to provide PBM services to its health plans from 2008 through the present. These PBM services included developing and offering formularies for Plaintiff's prescription plan, constructing and managing Plaintiff's pharmacy network (which included the PBMs' retail and mail-order pharmacies), processing pharmacy claims, and providing mail-order pharmacy services to Plaintiff.

414. In providing these services, Defendant CVS Caremark—in direct coordination with the Manufacturer Defendants and utilizing the false prices generated by the Insulin Pricing Scheme—determined the amounts Plaintiff paid for the at-issue medications. Plaintiff paid CVS Caremark for the at-issue drugs and paid those PBM Defendants to manage pharmacy benefits related to the at-issue drugs.

**I. Defendants Deceived Plaintiff**

415. At no time has either Defendant group disclosed the Insulin Pricing Scheme or the false list prices produced by it.

*The Manufacturer Defendants Deceived Plaintiff*

416. At all times during the relevant period, the Manufacturer Defendants knew that the list prices, net prices, and payors' net costs (purchase prices) generated by the Insulin Pricing Scheme were false, excessive, and untethered to any legal, competitive, or fair-market price.

417. The Manufacturer Defendants knew that these prices did not bear a reasonable relationship to the actual costs incurred or prices realized by Defendants, did not result from transparent or competitive market forces, and were artificially and arbitrarily inflated for the sole purpose of generating profits for Defendants.

418. The Defendants' business arrangement around insulin medications exhibits

the key features of oligopolies (*see* Fig. 14)—concentration of numerous competitors into a small group of firms that dominates the market, high barriers to new entry, ability to set and control prices, firm interdependence, and maximal revenues.

419. The Manufacturer Defendants also knew that payors, including Plaintiff, relied on the false list prices generated by the Insulin Pricing Scheme to pay for the at-issue drugs.

420. The Manufacturer and PBM Defendants further knew that Plaintiff—like any reasonable consumer and particularly one with fiduciary obligations to Beneficiaries—wanted and expected to pay a price reflecting the lowest fair market value for the drugs (which was not necessarily the same as the lowest price in the market, given that all prices were inflated due to the Insulin Pricing Scheme).

421. Despite this knowledge, the Manufacturer Defendants published list prices generated by the Insulin Pricing Scheme throughout the United States and Ohio through publishing compendia, in various promotional and marketing materials distributed by entities downstream in the drug supply chain, and directly to pharmacies, who then used these prices to set the amount that the pharmacies charged for the at-issue drugs.

422. The Manufacturer Defendants also publish these prices to the PBMs, who then use them to charge diabetics and payors, like Plaintiff, for the at-issue drugs.

423. By publishing their prices throughout Ohio, the Manufacturer Defendants held each of these prices out as a reasonable price on which to base the prices payors pay for the at-issue drugs.

424. These representations are false. The Manufacturer Defendants knew that their artificially inflated list prices were not remotely related to their cost, their fair market value in a competitive market, or the net price received for the at-issue drugs.

425. During the relevant period, the Manufacturer Defendants published prices in Ohio in the hundreds of dollars per dose for the same at-issue drugs that would have been profitable at less than \$10 per dose.

426. The Manufacturer Defendants also have publicly represented that they price the at-issue drugs according to each drug's value to the health care system and the need to fund innovation. For example, briefing materials prepared for CEO Dave Ricks as a panelist at the 2017 Forbes Healthcare Summit included "Reactive Key Messages" on pricing that emphasized the significant research and development costs for insulin. During the relevant period, executives from Sanofi and Novo Nordisk also falsely represented that research and development costs were key factors driving the at-issue price increases.<sup>77</sup>

427. To the contrary, between 2005 and 2018, Eli Lilly spent \$680 million on R&D costs related to Humalog while earning \$31.35 billion in *net* sales during that same period. In other words, Eli Lilly made more than 46 times its reported R&D costs on Humalog during this portion of the relevant period, i.e., R&D costs amounted to about 2% of *net* sales (whereas R&D costs for pharmaceuticals typically amount to around 20% of *total* revenues). Novo Nordisk has spent triple the amount it spends on R&D on stock buyouts and shareholder dividend payouts in recent years.<sup>78</sup>

428. The Senate Insulin Report found that the PBMs consider insulins to be "interchangeable" from "a clinical perspective" and that Manufacturers "focus their R&D

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<sup>77</sup> Drug Pricing Investigation, H.R. Comm. On Oversight and Reform, 117th Cong. (2021), <https://web.archive.org/web/20211215170722/https://oversight.house.gov/sites/democrats.oversight.house.gov/files/DRUG%20PRICING%20REPORT%20WITH%20APPENDIX%20v3.pdf> (last visited Jan. 10, 2023).

<sup>78</sup> *Id.*

efforts on new insulin-related devices, equipment, and other mechanical parts that are separate from insulin's formulation.”<sup>79</sup>

429. A House Oversight Committee staff report concluded that “drug companies’ claims that reducing U.S. prescription drug prices will harm innovation is overblown” and that “[m]any drug companies spent a significant portion of their R&D budget on finding ways to suppress generic and biosimilar competition while continuing to raise prices, rather than on innovative research.”<sup>80</sup>

430. In sum, the Manufacturer Defendants affirmatively withheld the truth from Plaintiff and specifically made misrepresentations in furtherance of the Insulin Pricing Scheme and to induce Plaintiff's reliance to purchase the at-issue drugs.

*The PBM Defendants Deceived Plaintiff*

431. The PBM Defendants ensured that the Manufacturer Defendants’ artificially inflated list prices harmed diabetics and payors by selecting high-priced at-issue drugs for preferred formulary placement and by requiring that their contracts with both pharmacies and with payors include such prices as the basis for payment.

432. The PBM Defendants perpetuate the use of the artificially inflated insulin prices because it allows them to obscure the actual price any entity in the drug pricing chain is paying for the at-issue drugs. This lack of transparency affords Defendants the opportunity to construct and perpetuate the Insulin Pricing Scheme, and to profit therefrom at the expense of Ohio payors, including Plaintiff.

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<sup>79</sup> Grassley & Wyden, *supra* note 4 at 5, 17.

<sup>80</sup> U.S. House of Reps., *Drug Pricing Investigation: Industry Spending on Buybacks, Dividends and Executive Compensation* (July 2021), <https://oversightdemocrats.house.gov/sites/democrats.oversight.house.gov/files/COR%20Staff%20Report%20-%20Pharmaceutical%20Industry%20Buybacks%20Dividends%20Compared%20to%20Research.pdf> (last visited Jan. 10, 2023).

433. Throughout the relevant time period, the PBMs have purposefully and consistently misrepresented that they negotiate with Manufacturer Defendants and construct formularies for the benefit of payors and patients to lower drug prices of the at-issue drugs and by promoting the health of diabetics. Representative examples include:<sup>81</sup>

- Defendant CVS Caremark has consistently stated in its annual reports that its design and administration of formularies are aimed at reducing the costs and improving the safety, effectiveness and convenience of prescription drugs. CVS Caremark has further stated that it maintains an independent panel of doctors, pharmacists and other medical experts to review and approve the selection of drugs based on safety and efficacy for inclusion on one of Caremark's template formularies and that CVS Caremark's formularies lower the cost of drugs.
- Likewise, Defendant Express Scripts has consistently represented that it works with clients, manufacturers, pharmacists and physicians to increase efficiency in the drug distribution chain, to manage costs in the pharmacy benefit chain and to improve members' health outcomes. Its annual reports consistently claim that in making formulary recommendations, Express Scripts' Pharmacy & Therapeutics Committee considers the drug's safety and efficacy, without any information on or consideration of the cost of the drug, including any discount or rebate arrangement that Express Scripts negotiates with the Manufacturer, and that Express Scripts fully complies with the P&T Committee's clinical recommendations regarding drugs that must be included or excluded from the formulary based on their assessment of safety and efficacy.
- Similarly, Defendant OptumRx has consistently stated in its annual reports over the past decade that OptumRx's rebate contracting and formulary management assist customers in achieving a low-cost, high-quality pharmacy benefit. It has consistently claimed that it promotes lower costs by using formulary programs to produce better unit costs, encouraging patients to use drugs that offer improved value and that OptumRx's formularies are selected for health plans based on their safety, cost and effectiveness.

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<sup>81</sup> CVS Health Annual Reports (Form 10-K) (FY 2010-2019); OptumRx Annual Reports (Form 10-K) (FY 2010-2019); Express Scripts Annual Reports (Form 10-K) (FY 2010-2019).



434. In addition to these general misrepresentations, the PBM Defendants have during and throughout the relevant period purposefully and consistently made misrepresentations about the at-issue medications. Representative examples include:

- In a public statement issued in November 2010, CVS Caremark represented that it was focused on diabetes to “help us add value for our PBM clients and improve the health of plan members . . . a PBM client with 50,000 employees whose population has an average prevalence of diabetes could save approximately \$3.3 million a year in medical expenditures.”<sup>82</sup>
- In 2010, Andrew Sussman, Chief Medical Officer of CVS Caremark, stated on national television that “CVS is working to develop programs to hold down [diabetes] costs.”<sup>83</sup>
- In a public statement issued in November 2012, CVS Caremark represented that formulary decisions related to insulin products “is one way the company helps manage costs for clients.”<sup>84</sup>
- In 2016, Glen Stettin, SVP and Chief Innovation Officer at Express Scripts, said in an interview with a national publication that “[d]iabetes is wreaking havoc on patients, and it is also a runaway driver of costs for payors . . . [Express Scripts] helps our clients and diabetes patients prevail over cost and care challenges created by this terrible disease.”<sup>85</sup> Mr. Stettin claimed that Express Scripts “broaden[s] insulin options for patients and bend[s] down the cost curve of what is currently the costliest class of traditional prescription drugs.”<sup>86</sup>

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<sup>82</sup> Chain Drug Review, *CVS Expands Extracare for Diabetes Products* (May 11, 2010), <https://www.chaindrugreview.com/cvs-expands-extracare-for-diabetes-products/> (last visited Jan. 15, 2023).

<sup>83</sup> CBS News, *Diabetes Epidemic Growing* (June 22, 2010, 11:29 AM), <https://www.cbsnews.com/news/diabetes-epidemic-growing/> (last visited Jan. 15, 2023).

<sup>84</sup> Jon Kamp & Peter Loftus, *CVS’ PBM Business Names Drugs It Plans to Block Next Year*, WSJ (Nov. 8, 2012), <https://www.wsj.com/articles/SB10001424127887324439804578107040729812454> (last visited Jan. 15, 2023).

<sup>85</sup> <https://www.bizjournals.com/stlouis/news/2016/08/31/express-scripts-launches-program-to-control.html> (last visited Jan. 15, 2023).

<sup>86</sup> Angela Mueller, *Express Scripts Launches Program to Control Diabetes Costs*, St. Louis Bus. J. (Aug. 31, 2016), <https://drugstorenews.com/pharmacy/express-scripts-implements-latest-diabetes-care-value-program> (last visited Jan. 15, 2023).

- In a 2018 Healthline interview, Mark Merritt, President of the PBM trade association PCMA represented that: “[Through their formulary construction], PBMs are putting pressure on drug companies to reduce insulin prices.”<sup>87</sup>
- CVS Caremark’s Chief Policy and External Affairs Officer claimed in the April 2019 hearings that CVS Caremark “has taken a number of steps to address the impact of insulin price increases. We negotiate the best possible discounts off the manufacturers’ price on behalf of employers, unions, government programs, and beneficiaries that we serve.”<sup>88</sup>
- Sumit Dutta, SVP and Chief Medical Officer of OptumRx, testified to Congress that for “insulin products . . . we negotiate with brand manufacturers to obtain significant discounts off list prices on behalf of our customers.”<sup>89</sup>
- The PCMA’s website acknowledges, “the insulin market is consolidated, hindering competition and limiting alternatives, leading to higher list prices on new and existing brand insulins,” but then misleadingly claims that “PBMs work hard to drive down costs using formulary management and rebates.”<sup>90</sup>

435. The PBM Defendants not only falsely represent that they negotiate with the Manufacturer Defendants to lower the price of the at-issue diabetes medications for *payors*, but also for diabetic *patients* as well. Representative examples include:

- Express Scripts’ code of conduct, effective beginning in 2015, states: “At Express Scripts we’re dedicated to keeping our promises to *patients and clients* . . . This commitment defines our culture, and all our collective efforts are focused on our mission to make the use of prescription drugs safer and more affordable.”<sup>91</sup> (emphasis added)

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<sup>87</sup> *Insulin Prices: Are PBMs and Insurers Doing Their Part?*, <https://www.hmpgloballearningnetwork.com/site/frmc/article/insulin-prices-are-pbms-and-insurers-doing-their-part> (last visited Jan. 15, 2023).

<sup>88</sup> *Priced Out of a Lifesaving Drug*, *supra* note 56.

<sup>89</sup> *Id.*

<sup>90</sup> PCMA, *PCMA on National Diabetes Month: PBMs Lowering Insulin Costs, Providing Support to Patients* (Nov. 16, 2020), <https://www.pcmanet.org/pcma-on-national-diabetes-month-pbms-lowering-insulin-costs-providing-support-to-patients/> (last visited Jan. 15 2023); Visante, *Insulins: Managing Costs with Increasing Manufacturer Prices* (2020), [https://www.pcmanet.org/wp-content/uploads/2020/08/PCMA\\_Visante-Insulins-Prices-and-Costs-.pdf](https://www.pcmanet.org/wp-content/uploads/2020/08/PCMA_Visante-Insulins-Prices-and-Costs-.pdf).

<sup>91</sup> Express Scripts, *Code of Conduct*, <https://www.express-scripts.com/aboutus/codeconduct/ExpressScriptsCodeOfConduct.pdf> (last visited Jan. 10, 2023).

- Amy Bricker—former President of Express Scripts and PCMA board member; now an executive with CVS Health—testified to Congress in April 2019: “At Express Scripts we negotiate lower drug prices with drug companies on behalf of our clients, *generating savings that are returned to patients* in the form of lower premiums and reduced out-of-pocket costs.”<sup>92</sup> (emphasis added)
- Ms. Bricker also testified that “Express Scripts remains committed to . . . patients with diabetes and creating affordable access to their medications.”<sup>93</sup>
- OptumRx CEO John Prince testified to the Senate: “We *reduce the costs of prescription drugs* [and] we are leading the way to ensure that *those discounts directly benefit consumers*. . . . OptumRx’s pharmacy care services business is *achieving better health outcomes for patients, lowering costs* for the system, and *improving the healthcare experience for consumers*. . . . OptumRx negotiates better prices with drug manufacturers *for our customers and for consumers*.”<sup>94</sup> (emphasis added)
- In its 2017 Drug Report, CVS Caremark stated that the goal of its pharmacy benefit plans is to ensure “that the cost of a drug is aligned with the value it delivers in terms of patient outcomes . . . in 2018, we are doing even more to help keep drugs affordable with our new Savings Patients Money initiative.”<sup>95</sup>
- The PCMA website touts PBMs as “the only entity in the prescription drug supply and payment chain dedicated to reducing drug costs” and (contradicting the PBM representatives’ Congressional testimony), that “when new manufacturers enter the market at a lower list price, PBMs use the competition to drive costs down.”<sup>96</sup>

436. Not only have the PBM Defendants intentionally misrepresented that they use their market power to save payors money, but they have specifically and falsely disavowed that their conduct drives prices higher. Representative examples include:

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<sup>92</sup> *Priced Out of a Lifesaving Drug*, *supra* note 56.

<sup>93</sup> *Id.*

<sup>94</sup> Grassley & Wyden, *supra* note 4—*Hearing Transcript* at 174, <https://www.finance.senate.gov/imo/media/doc/435631.pdf> (last visited Jan. 11, 2023).

<sup>95</sup> CVS Health, *2017 Drug Trend Report* (Apr. 5, 2018), <https://payorsolutions.cvshealth.com/insights/2017-drug-trend-report> (last visited Jan. 10, 2023).

<sup>96</sup> PCMA, *PBMs Reduce Insulin Costs: PBMs are working to improve the lives of patients living with diabetes and their families*, <https://www.pcmamet.org/insulin-managing-costs-with-increasing-manufacturer-prices/> (last visited Jan. 10, 2023).

- On an Express Scripts' earnings call in February 2017, CEO Tim Wentworth stated: "Drugmakers set prices, and we exist to bring those prices down."<sup>97</sup>
- Larry Merlo, head of CVS Caremark sounded a similar refrain in February 2017: "Any suggestion that PBMs are causing prices to rise is simply erroneous."<sup>98</sup>
- In 2017, Express Scripts' Wentworth went on CBS News to argue that PBMs play no role in rising drug prices, stating that PBMs work to "negotiate with drug companies to get the prices down."<sup>99</sup>
- When asked by Congress if PBM-negotiated rebates and discounts were causing the insulin price to increase, OptumRx's Sumit Dutta answered, "we can't see a correlation when rebates raise list prices."<sup>100</sup>
- In 2019, when testifying Congress on the rising price of insulins, Amy Bricker—then with Express Scripts, now with CVS—testified, "I have no idea why the prices [for insulin] are so high, none of it is the fault of rebates."<sup>101</sup>

437. All of the PBM Defendants' public statements regarding insulin pricing have been consistent with the misrepresentations above (and those detailed below). None has contradicted those misrepresentations and none has revealed the Insulin Pricing Scheme.

438. Although Plaintiff's employees responsible for managing Plaintiff's health plans were not following the various Congressional hearings when they occurred and were not exposed to all of the misrepresentations detailed above (or all of those detailed below), all public pronouncements by Defendants were consistent with those misrepresentations.

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<sup>97</sup> Samantha Liss, *Express Scripts CEO Addresses Drug Pricing 'Misinformation'*, St. Louis Post-Dispatch (Feb. 17, 2017), [https://www.stltoday.com/business/local/express-scripts-ceo-addresses-drug-pricing-misinformation/article\\_8c65cf2a-96ef-5575-8b5c-95601ac51840.html](https://www.stltoday.com/business/local/express-scripts-ceo-addresses-drug-pricing-misinformation/article_8c65cf2a-96ef-5575-8b5c-95601ac51840.html) (last visited Jan. 11, 2023).

<sup>98</sup> Lynn R. Webster, *Who Is To Blame For Skyrocketing Drug Prices?*, The Hill (July 27, 2017, 11:40 AM), <https://thehill.com/blogs/pundits-blog/healthcare/344115-who-is-to-blame-for-skyrocketing-drug-prices> (last visited Jan. 11, 2023).

<sup>99</sup> CBS News, *Express Scripts CEO Tim Wentworth Defends Role of PBMs in Drug Prices* (Feb 7, 2017), <https://www.cbsnews.com/news/express-scripts-tim-wentworth-pbm-rising-drug-prices-mylan-epipen-heather-bresh/> (last visited Jan. 11, 2023).

<sup>100</sup> *Priced Out of a Lifesaving Drug*, *supra* note 56.

<sup>101</sup> *Id.*

439. Plaintiff's direct interactions with its PBM, CVS Caremark, were consistent with those misrepresentations, which were made in furtherance of, and in order to conceal, the Insulin Pricing Scheme. For example:

a. A 2019 Annual Review conducted by CVS Caremark touted that it was [REDACTED]

[REDACTED]  
[REDACTED]

b. In announcing its new formularies in 2022 to Plaintiff CVS Caremark acknowledged that [REDACTED]

[REDACTED] CVS Caremark further stated

[REDACTED]  
[REDACTED]

[REDACTED] CVS further touted an anticipated [REDACTED]

[REDACTED]  
[REDACTED]

[REDACTED] CVS Caremark concluded this summary to Plaintiff by re-iterating its promise to Plaintiff [REDACTED]

[REDACTED]  
[REDACTED]

c. In late 2022, CVS Caremark provided Plaintiff with [REDACTED]

[REDACTED]  
[REDACTED] CVS Caremark continued to promise that it [REDACTED]

[REDACTED] and further vowed to continue [REDACTED]

[REDACTED]

CVS Caremark stated that one of its goals was [REDACTED]  
[REDACTED]. But CVS Caremark went further and noted, [REDACTED]  
[REDACTED]  
[REDACTED] CVS  
Caremark also noted that it [REDACTED]  
[REDACTED]  
[REDACTED] CVS Caremark concluded  
by re-stating its promise to Plaintiff [REDACTED]  
[REDACTED]  
[REDACTED]

- d. CVS Caremark has also consistently represented to Plaintiffs that it and its Beneficiaries can get an even greater savings on prescription drugs by utilizing its mail order pharmacies. In a 2008 marketing document provided to Plaintiff by CVS Caremark, the PBM represented [REDACTED]  
[REDACTED]

CVS Caremark further touted, [REDACTED]  
[REDACTED]  
[REDACTED]

- e. In a 2017 marketing piece provided to Plaintiff, CVS Caremark promotes [REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED].

440. While bombarding Plaintiff with misrepresentations and half-truths like those above, none of the PBMs revealed the details of their relationships with the Manufacturer Defendants or the existence of the Insulin Pricing Scheme.

441. Throughout the relevant period, the PBM Defendants have consistently and repeatedly represented that: (1) their interests are aligned with their payor clients; (2) they work to lower the price of the at-issue drugs and, in doing so, achieve substantial savings for diabetics and payors; and (3) that monies they receive from manufacturers and their formulary choices are for the benefit of payors and diabetics.

442. The PBM Defendants understand that payors like Plaintiff rely on the PBMs to achieve the lowest prices for the at-issue drugs and to construct formularies designed to improve access to medications. Plaintiff did so.

443. Throughout the relevant period, the PBM Defendants also falsely claimed they are transparent about the Manufacturer Payments and that the amounts remit (or not) to payors. In fact, the PBM Defendants' disclosures of their ties to the Manufacturer Defendants were vague and equivocal. Their manner of defining "rebates" in payor contracts was illusory and subject to indeterminate conditions and exceptions. The PBM Defendants thereby facilitated and obtained secret Manufacturer Payments far above and beyond the amount of "rebates" remitted to payors.

444. The PBM Defendants' internal processes and accounting were and are abstruse and opaque, allowing them to overtly mislead the public and payors like Plaintiff.

445. In 2011, for example, OptumRx's President stated: "We want our clients to fully understand our pricing structure . . . [e]very day we strive to show our commitment

to our clients, and one element of that commitment is to be open and honest about our pricing structure.”<sup>102</sup>

446. In a 2017 CBS News interview, Express Scripts’ CEO represented, among other things, that Express Scripts was “absolutely transparent” about the Manufacturer Payments they receive and that payors “know exactly how the dollars flow” with respect to these Manufacturer Payments.<sup>103</sup>

447. When testifying before the Senate Finance Committee, CVS Executive Vice President Derica Rice stated, “[A]s it pertains to transparency overall, we at CVS Caremark are very supportive. We provide full visibility to our clients of all our contracts and the discounts that we negotiate on their behalf. . . . And transparency—today we report and fully disclose not only to our clients, but to CMS [Medicare].”<sup>104</sup>

448. Testifying at the same hearing, Steve Miller of Cigna (Express Scripts) claimed “we are a really strong proponent for transparency for those who pay for health care. So the patient should know exactly what they are going to pay. Our plan sponsors should know exactly what is in their contract.”<sup>105</sup>

449. John Prince of OptumRx chimed in, “Senator, if our discounts were publicly

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<sup>102</sup> UnitedHealth Group, *Prescription Solutions by OptumRx Receives 4th Consecutive TIPPS Certification for Pharmacy Benefits Transparency Standards* (Sept. 13, 2011), <https://web.archive.org/web/20210805182422/https://www.unitedhealthgroup.com/newsroom/2011/0913tipps.html> (last visited Jan. 11, 2023). *Also see, e.g.*, published version of press release at <https://www.businesswire.com/news/home/20110913006224/en/Prescription-Solutions-by-OptumRx-Receives-4th-Consecutive-TIPPSSM-Certification-for-Pharmacy-Benefits-Transparency-Standards> (last visited Jan. 11, 2023).

<sup>103</sup> CBS News, *supra* note 99.

<sup>104</sup> Grassley & Wyden, *supra* note 4—*Hearing Transcript* at 28, 32, <https://www.finance.senate.gov/imo/media/doc/435631.pdf> (last visited Jan. 11, 2023).

<sup>105</sup> *Id.* at 32.



available, it would hurt our ability to negotiate effectively. Our discounts are transparent to our clients.”<sup>106</sup>

450. When testifying before Congress in April 2019, Amy Bricker, then a Senior Vice President of Defendant Express Scripts, touted transparency with payors and echoed Mr. Prince’s need for confidentiality around discounts:<sup>107</sup>

Ms. Bricker. The rebate system is 100 percent transparent to the plan sponsors and the customers that we service. To the people that hire us, employers of America, the government, health plans, what we negotiate for them is transparent to them. . . The reason I’m able to get the discounts that I can from the manufacturer is because it’s confidential [to the public].

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Mr. Sarbanes. Yeah, because it’s a secret. What about if we made it completely transparent? Who would be for that?

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Ms. Bricker. Absolutely not . . . [i]t will hurt the consumer. . . prices will be held high.

451. As recently as May 2022, JC Scott—President of the PBM trade group PCMA—testified as follows before the Senate Commerce Committee:

PBMs are proud of the work they do to reduce prescription drug costs, expand affordable access to medications, and improve patient outcomes. PBMs negotiate with drug companies to lower prescription drug costs PBMs advocate for patients in the fight to keep prescription drugs accessible and affordable.

Mirroring the PCMA website (§ 435 *supra*), Mr. Scott also testified, “The PBM industry is the only stakeholder in the chain dedicated to seeking lower costs.”

452. During the relevant period—as seen above—PBM Defendants represented to

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<sup>106</sup> *Id.*

<sup>107</sup> *Priced Out of a Lifesaving Drug*, *supra* note 56.

Plaintiff that they constructed formularies and negotiated with the Manufacturer Defendants for the benefit of payors and patients to maximize drug cost savings while promoting the health of diabetics.

453. Throughout the relevant period, the PBMs consistently made similar misrepresentations directly to Ohio payors, including Cleveland, through bid proposals, member communications, invoices, formulary change notifications, and through extensive direct-to-consumer pull through efforts engaged in with the Manufacturers.

454. These representations were false—the Manufacturer and PBM Defendants in fact coordinated to publish the false prices and to construct the PBM formularies, causing the price of the at-issue drugs to skyrocket. For example:

- a. In 2018, the U.S. spent \$28 billion (USD) on insulin compared with \$484 million in Canada. The average American insulin user spent \$3490 on insulin in 2018 compared with \$725 among Canadians.
- b. Diabetics who receive their medications from federal programs that do not utilize PBMs also pay significantly less. In December 2020, the United States House of Representatives Committee on Oversight and Reform issued a Drug Pricing Investigation Report finding that federal health care programs that negotiate directly with the Manufacturers (such as the Department of Veterans Affairs), and thus are outside the PBM Defendants' scheme, paid \$16.7 billion less from 2011 through 2017 for the at-issue drugs than the Medicare Part D program, which relies on the PBM Defendants to set their at-issue drug prices.

455. Defendants knew their representations were false when they made them and coordinated to affirmatively withhold the truth from payors, including Plaintiff.

456. Defendants concealed the falsity of their representations by closely guarding their pricing negotiations, structures, agreements, sales figures, and the flow of money and other consideration between them.

457. The Defendants have never revealed the full amount of any drug-specific Manufacturer Payments exchanged between them. Despite the claims of transparency to Plaintiff and to the public and despite Plaintiff's contracts with OptumRx and Express Scripts, Plaintiff does not know, and cannot learn, of the full extent of the Manufacturer Payments and other agreements between PBMs and the Manufacturer Defendants.

458. The PBM Defendants do not disclose the terms of the agreements they make with the Manufacturers or the Manufacturer Payments they receive. Nor do they disclose the details related to their agreements (formal or otherwise) with pharmacies. All of these revenue streams are beyond the scope of the payors' contractual audit rights.

459. Further, although PBMs negotiate drug-specific rebates with Manufacturers,<sup>108</sup> the PBM rebate payments to payor clients and summaries of such payments are in the aggregate, rather than on a drug-by-drug basis. It is impossible for payors like Plaintiff to tease out drug-specific rebates, much less the other undisclosed Manufacturer Payments. This allowed the PBM Defendants to hide the large Manufacturer Payments that they receive for the at-issue diabetes medications.

460. The PBM Defendants have gone so far as to sue governmental entities to block the release of details on their pricing agreements with the Manufacturers and pharmacies.

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<sup>108</sup> Grassley & Wyden, *supra* note 4 at 40.

461. Even when audited by payors, the PBM Defendants routinely refuse to disclose their agreements with the Manufacturers and pharmacies by relying on overly broad confidential agreements and claims of trade secrets and by erecting other unnecessary roadblocks and restrictions.

462. Beneficiaries of the Plaintiff's health plans have no choice but to pay prices flowing from Defendants' inflated list prices because Beneficiaries need these medications to survive and the Manufacturer Defendants make virtually all diabetes medications available in the United States. The list prices generated by the Defendants' coordinated efforts directly impact out-of-pocket costs at the point of sale.

463. In sum, the entire insulin pricing structure created by the Defendants—from the false prices to the Manufacturers' misrepresentations related to the reasons behind the prices, to the inclusion of the false prices in payor contracts, to the non-transparent Manufacturer Payments, to the misuse of formularies, to the PBMs' representations that they work to lower prices and promote the health of diabetics—is unconscionable, deceptive, and immensely lucrative.

464. Plaintiff did not know, because the Defendants affirmatively concealed, (1) that the Manufacturers and PBMs coordinated to create the PBM formularies in exchange for money and other consideration; (2) that the list prices were falsely inflated; (3) that the list prices were manipulated to satisfy PBM profit demands; (4) that the list prices and net costs (purchase prices) paid by Plaintiff bore no relationship to the fair market value of the drugs themselves or the services rendered by the PBMs in coordinating their pricing; or (5) that the entire insulin pricing structure Defendants created was false.

**J. The Insulin Pricing Scheme Has Damaged Plaintiff**

465. Plaintiff provides health and pharmacy benefits to its Beneficiaries, including employees, retirees, and their dependents, who have numbered in the thousands throughout the relevant period.

466. One of the benefits that Plaintiff offers its Beneficiaries through its employee health plans is payment of a significant portion of the Beneficiaries' prescription drug purchases.

467. Plaintiff has for years interacted with and/or engaged in business with the PBM Defendants concerning pharmacy services and the at-issue diabetes medications.

468. Since at least 2009, Plaintiff had a PBM service agreement in place with CVS Caremark.

469. Since its initial contract with CVS Caremark, Plaintiff has received bids for pharmacy services from CVS Caremark, Express Scripts, and OptumRx. In providing those bids each made representations in furtherance of the Insulin Pricing Scheme.

470. At all of these points in time, Plaintiff was unaware of the Insulin Pricing Scheme.

471. Plaintiff relied on Defendants' statements and material omissions made in furtherance of the Insulin Pricing Scheme.

472. Plaintiff relied on Defendants' misrepresentations in paying for the at-issue diabetes medications at prices that would have been lower but for the Insulin Pricing Scheme.

473. Since 2009, Plaintiff has spent millions of dollars on the at-issue diabetes medications.

474. CVS Caremark failed to adhere to principles of good faith and fair dealing in carrying out its PBM contracts with Plaintiff. Its relationship with Plaintiff was and is inherently unbalanced and its contracts adhesive. CVS Caremark has had superior bargaining power and superior knowledge of its relationships with the Manufacturer Defendants, including those that ultimately dictate the drug costs Plaintiff incurred. Although Defendants were supplying a vital service of a quasi-public nature, they both exploited their superior positions to mislead Plaintiff and thwart its expectations, all at great expense to Plaintiff.

475. The Defendants' misrepresentations, omissions, and misconduct—including and as manifested in the Insulin Pricing Scheme—directly and proximately caused economic damage to Plaintiff as a payor/purchaser of Defendants' at-issue medications.

476. A substantial proportion of the money Plaintiff spent on diabetes medications is attributable to Defendants' inflated prices, which did not arise from competitive market forces but, instead, arise directly from the Insulin Pricing Scheme.

477. Because of Defendants' success in concealing the Insulin Pricing Scheme through act and omission, no payor, including Plaintiff, knew, should have known, or could have known during the relevant period that the prices for the at-issue diabetes medications were (and remain) artificially inflated due to the Defendants' scheme.

478. As a result, despite receiving some rebates and incurring drug costs based on discounts off list prices, Plaintiff has unknowingly overpaid for the Manufacturer Defendants' diabetes medications, which would have cost less but for the Insulin Pricing Scheme.

479. In short, the Insulin Pricing Scheme has directly and proximately caused Plaintiff to substantially overpay for diabetes medications.

480. Because Defendants continue to generate exorbitant, unfair, and deceptive prices for the at-issue drugs through the Insulin Pricing Scheme, the harm to Plaintiff is ongoing.

**K. Defendants' Recent Efforts in Response to Rising Insulin Prices**

481. In reaction to mounting political and public outcry, Defendants have taken action both on Capitol Hill and in the public relations space.

482. First, in response to public criticism, Defendants have increased their spending to spread their influence in Washington D.C.

483. For example, in recent years Novo Nordisk's political action committee ("PAC") has doubled its spending on federal campaign donations and lobbying efforts. In 2017 alone, Novo Nordisk spent \$3.2 million lobbying Congress and federal agencies, its biggest ever investment in directly influencing U.S. policymakers. Eli Lilly and Sanofi also have contributed millions of dollars through their PACs in recent years.

484. Second, Defendants have recently begun publicizing programs ostensibly aimed at lowering the cost of insulins.

485. These affordability measures fail to address the structural issues that caused the price hikes. Rather, these are public relations measures that do not solve the problem.

486. For example, in March 2019, Defendant Eli Lilly announced that it would produce an authorized generic version of Humalog, "Insulin Lispro," and promised that it would "work quickly with supply chain partners to make [the authorized generic] available in pharmacies as quickly as possible."

487. However, in the months after Eli Lilly's announcement, reports raised questions about the availability of "Insulin Lispro" in local pharmacies.

488. Following this the staff of the Offices of U.S. Senators Elizabeth Warren and

Richard Blumenthal prepared a report examining the availability of this drug. The investigative report, *Inaccessible Insulin: The Broken Promise of Eli Lilly's Authorized Generic*, concluded that Eli Lilly's lower-priced, authorized generic insulin is widely unavailable in pharmacies across the country, and that the company has not taken meaningful steps to increase insulin accessibility and affordability.<sup>109</sup>

489. Eli Lilly did lower the price of Lispro by 40% effective January 1, 2022; but it is not included in any of the PBM Defendants' formularies as of January 2023.

490. In 2019, Novo Nordisk partnered with Walmart to offer ReliOn brand insulins for a discounted price at Walmart. However, experts have warned that the Walmart/Novo Nordisk insulins are not substitutes for most diabetics' regular insulins and should only be used in an emergency or when traveling. In particular, for many diabetics, especially Type 1 diabetics, these insulins can be dangerous. In any event, ReliOn is not included in any of the PBM Defendants' formularies as of January 2023.

491. Thus, Defendants' "lower priced" insulin campaigns have not addressed the problem and the PBMs continue to exclude drugs with lower list prices despite their assurances of cost-savings for payors and Beneficiaries.

492. Likewise, the FDA in 2020 approved the biosimilar Insulin Glargine-yfgn (branded as Semglee), which is manufactured and sold by newcomers to the market—Viatris and Biocon Biologics.<sup>110</sup> Insulin Glargine-yfgn (Semglee) is interchangeable with Defendant Sanofi's Lantus product, and, according Viatris, its list price is three times less

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<sup>109</sup> Sen. Elizabeth Warren & Sen. Richard Blumenthal, *Inaccessible Insulin: The Broken Promise of Eli Lilly's Authorized Generic*, (Dec. 2019), <https://www.warren.senate.gov/imo/media/doc/Inaccessible%20Insulin%20report.pdf> (last visited Jan. 12, 2023).

<sup>110</sup> As explained in n.5, insulin now is regulated as a biologic rather than a drug. Biosimilars are analogous to generic drugs—approved versions of original products that are virtually identical to, and interchangeable with, the original product.



than Lantus. However, it had not been included in the formularies for Defendants CVS Caremark or OptumRx as of January 2023.

493. Most recently, the Manufacturers announced they will reduce the prices of certain insulin and analog drugs with Price Cuts set to take effect in late 2023 and 2024. As explained above in ¶¶ 245–251, however, these Price Cuts are insufficient and will not mitigate Plaintiff's past damages or prevent further losses moving forward.

## **V. TOLLING OF THE STATUTES OF LIMITATIONS**

494. Plaintiff has diligently pursued and investigated its claims. Through no fault of its own, Plaintiff did not learn and—given Defendants coordinated, successful efforts to mislead Plaintiff—could not until recently have learned the factual bases for its claims or the injuries suffered therefrom. Consequently, the following tolling doctrines apply.

### **A. Discovery Rule**

495. Plaintiff was not aware of the Insulin Pricing Scheme until shortly before filing this Complaint. Plaintiff was unaware that it was economically injured and unaware that any economic injury was wrongfully caused. Nor did Plaintiff possess sufficient information concerning the injury complained of here, or its cause, to put Plaintiff or any reasonable person on notice that actionable conduct might have occurred.

496. The PBM and Manufacturer Defendants refused to disclose the actual prices of diabetes medications realized by Defendants or the details of the Defendants' negotiations and payments between each other or their pricing structures and agreements—Defendants labeled these trade secrets, shrouded them in confidentiality agreements, and circumscribed payor audit rights to protect them.

497. Each Defendant group affirmatively and fraudulently blamed the other for the price increases described herein, both during their Congressional testimonies and

through the media. All disavowed wrongdoing and falsely claimed that their dealings with payors like Plaintiff were honest and transparent.

498. Plaintiff did not discover and could not have discovered until shortly before filing this Complaint facts sufficient to cause it or any reasonable person to suspect that Defendants were engaged in the Insulin Pricing Scheme or that Plaintiff had suffered economic injury as a result of any or all Defendants' wrongdoing. Given Defendants' individual and coordinated efforts to obscure and conceal their misconduct, earlier diligent inquiry would not have disclosed the true facts had Plaintiff been aware of any cause to undertake such an inquiry.

499. Even today, lack of transparency in the pricing of diabetes medications and the arrangements, relationships, and agreements between and among the Manufacturer Defendants and the PBM Defendants, i.e., the Insulin Pricing Scheme, continue to obscure the full extent of Defendants' unlawful conduct from Plaintiff and the general public.

500. For these reasons, the applicable statutes of limitations did not begin to run until 2022, at the earliest.

#### **B. Fraudulent Concealment**

501. Through the acts, omissions, and representations alleged throughout this Complaint, Defendants individually and through their conspiracy fraudulently concealed the fact of Plaintiff's economic injury and its cause.

502. Defendants' acts, omissions and representations were calculated to lull and induce payors, including Plaintiff, into forbearing legal action or any inquiry that might lead to legal action. Defendants' acts, omissions, and representations were intended to and in fact did prevent Plaintiff from discovering operative facts supporting its claims.

503. Plaintiff acted diligently in pursuing this action once it became aware of facts sufficient to place it on notice of the fact that it might have been harmed and that such harm might have been attributable to misconduct by each or all Defendants, including through Defendants' coordinated efforts to implement and to conceal the Insulin Pricing Scheme.

504. Accordingly, all applicable statutes of limitation have been tolled.

**C. Equitable Estoppel & Equitable Tolling**

505. Defendants were under a continuous duty to disclose to Plaintiff the true character, quality, and nature of the prices upon which payments for diabetes medications were based, and the true nature of the services being provided—all of which would be and are now material to Plaintiff.

506. Instead of disclosing these facts, Defendants knowingly misrepresented and concealed them with a reasonable expectation that Plaintiff would act upon the misrepresentations and omissions.

507. Being unaware of the true facts, being unaware of the economic harm it was suffering, and having no cause to inquire further, Plaintiff did indeed rely in good faith to its detriment on Defendants' misrepresentations and omissions.

508. In short, through Defendants' acts, omissions, and representations as alleged throughout this Complaint, Defendants knowingly misrepresented and concealed material facts with the expectation that Plaintiff would act upon them and would be misled thereby, which Plaintiff did in good faith and to its detriment.

509. Plaintiff acted diligently in pursuing this action once it became aware of facts sufficient to place it on notice of the fact that it might have been harmed and that such harm might have been attributable to misconduct by each or all Defendants,

including through Defendants' coordinated efforts to implement and to conceal the Insulin Pricing Scheme. However, Defendants' misconduct served as an extraordinary circumstance that stood in Plaintiff's way and prevented Plaintiff from filing earlier.

510. Accordingly, Defendants are equitably estopped from relying on any statutes of limitations in defense of this action and all statutes of limitations have been equitably tolled.

#### **D. Continuing Violations**

511. Defendants' acts, omissions, and misrepresentations alleged throughout this Complaint have continued to the present day.

512. Defendants' systematic misconduct constitutes a continuous, unbroken violation of the law that has caused, and continues to cause, continuous economic harm to Plaintiff.

513. Had Defendants at any time ceased their wrongful conduct, further injury would have been avoided

514. Accordingly, all applicable statutes of limitations are tolled.

### **VI. CLAIMS FOR RELIEF**

#### **Count One**

#### **Violations of the Racketeer Influenced and Corrupt Organizations Act ("RICO")**

##### **18 U.S.C. § 1962(c)**

(Against Defendants Eli Lilly, Novo Nordisk, Sanofi, and CVS Caremark)

515. Plaintiff re-alleges and incorporates by reference all of the allegations in the preceding paragraphs and those in ¶¶ 576-80, 587-94, 597-610, and 616-26.

516. Plaintiff brings this count against CVS Caremark (as defined in ¶ 110) and the Manufacturer Defendants—Eli Lilly, Novo Nordisk and Sanofi—for violations of 18 U.S.C. § 1962(c).

517. Defendants Eli Lilly, Novo Nordisk, Sanofi, and CVS Caremark are (1) culpable “persons” who (2) willfully and knowingly (3) committed and conspired to commit two or more acts of mail and wire fraud (4) through a “pattern” of racketeering activity that (5) involves an “association in fact” enterprise, (6) the results of which had an effect on interstate commerce.

**A. Defendants Are Culpable “Persons” Under RICO**

518. Defendants Eli Lilly, Novo Nordisk, Sanofi, and CVS Caremark, separately, are “persons” as that term is defined in 18 U.S.C. § 1961(3) because each is capable of holding a legal or beneficial interest in property.

519. Each one of Defendants Eli Lilly, Novo Nordisk, Sanofi, and CVS Caremark are separate entities and “persons” that are distinct from the RICO enterprises alleged below.

**B. The Manufacturer–PBM RICO Enterprises**

520. For the purposes of this claim, the RICO enterprises are three separate associations-in-fact each consisting of CVS Caremark and one of the Manufacturer Defendants, including those entities’ directors, employees, and agents: the Eli Lilly-CVS Caremark Enterprise; the Eli Lilly-CVS Caremark Enterprise; and the Novo Nordisk-CVS Caremark Enterprise.

521. These association-in-fact enterprises are collectively referred to herein as the “Manufacturer–PBM Enterprises.”

522. Each Manufacturer–PBM Enterprise is a separate, ongoing, and continuing business organization consisting of corporations and individuals associated for the common purpose of manufacturing, selling, and facilitating the purchase of the Manufacturer Defendants’ products, including the at-issue drugs. For example:

- a. The Eli Lilly-CVS Caremark Enterprise associates for the common purpose of manufacturing, selling, distributing, and facilitating the purchase of Eli Lilly medications including Prozac, Cymbalta, and Zyprexa, as well as the at-issue Eli Lilly insulin and insulin-analog medications (Trulicity, Humulin N, Humulin R, Humalog, and Basaglar), which are Eli Lilly's primary source of revenue.
- b. The Novo Nordisk-CVS Caremark Enterprise associates for the common purpose of manufacturing, selling, distributing, and facilitating the purchase of Novo Nordisk medications for the treatment of obesity, hemophilia, and hormone imbalance, as well as the at-issue Novo Nordisk insulin and insulin-analog medications (Novolin R, Novolin N, Novolog, Levemir, Tresiba, Victoza, and Ozempic), which account for more than three-quarters of Novo Nordisk's revenue.
- c. The Sanofi-CVS Caremark Enterprise associates for the common purpose of manufacturing, selling, distributing, and facilitating the purchase of Sanofi medications including Ambien, Plavix, and Dupixent, as well as the at-issue Sanofi insulin and insulin-analog medications (Lantus, Toujeo, Apidra, and Soliqua).

523. Each Manufacturer-PBM Enterprise engaged in the shared purpose of exchanging false list prices and secret Manufacturer Payments for preferred formulary positions for the at-issue drugs in order to control the market for diabetes medications and profit off diabetics and payors, including the Plaintiff.

524. The members of each enterprise are bound by contractual relationships, financial ties, and the ongoing coordination of activities.

525. There also is a common communication network by which the members of each enterprise share information and meet on a regular basis. These communications include, but are not limited to, communications relating to the use of false list prices for the at-issue diabetes medications and the regular flow of Manufacturer Payments from each Manufacturer Defendant to CVS Caremark in exchange for formulary placement.

526. Each Manufacturer-PBM Enterprise functions as continuing but separate unit separate and apart from the pattern of racketeering activity in which it engages. Each Manufacturer-PBM Enterprise, for example, engages in the manufacture, distribution

and sale of medications and other products other than the at-issue insulin and insulin-analog medications. Additionally, each Manufacturer engages in conduct other than mail and wire fraud in furtherance of the Insulin Pricing Scheme.

527. At all relevant times, each of the Manufacturer–PBM Enterprises was operated and conducted for unlawful purposes by each Manufacturer Defendant and CVS Caremark, namely, carrying out the Insulin Pricing Scheme.

528. Each Manufacturer–PBM Enterprise derived secret profits from these activities that were greater than those any one of the Manufacturer Defendants or CVS Caremark could obtain absent their misrepresentations regarding their non-transparent pricing schemes.

529. To accomplish this common purpose, each Manufacturer Defendant periodically and systematically inflated the prices of the at-issue drugs and then secretly paid a significant, yet undisclosed, portion of this inflated price back to CVS Caremark in the form of Manufacturer Payments.

530. Each Manufacturer–PBM Enterprise did so willfully and with knowledge that Plaintiff paid for the at-issue drugs at prices directly based on the false list prices.

531. Each Manufacturer–PBM Enterprise's inflation of the list prices and secret Manufacturer Payments was a quid pro quo exchange for preferred formulary placement.

532. Each Manufacturer–PBM Enterprise concealed from Plaintiff that these false prices and secret Manufacturer Payments resulted in each Manufacturer gaining formulary access without requiring significant price reductions and resulted in higher profits for CVS Caremark, whose earnings increase the more inflated the price is and the more payment it receives from each Manufacturer Defendant.

533. Each Manufacturer–PBM Enterprise also shares a common purpose of perpetuating the use of the false list prices for the at-issue drugs as the basis for the price that payors, including the Plaintiff, and diabetics pay for diabetes medications.

534. The Manufacturer Defendants would not be able to offer large pricing spreads to CVS Caremark in exchange for favorable formulary positions without the use of the false list prices as the basis for the price paid by diabetics and payors, including the Plaintiff, for the at-issue drugs.

535. CVS Caremark shares this common purpose because nearly all the revenue and profit generated from the at-issue drugs is tied to the false inflated prices generated by the Insulin Pricing Scheme. Without diabetics and payors, including the Plaintiff, paying for diabetes medications based on the inflated list prices, their profits from the Insulin Pricing Scheme would decrease.

536. As a result, CVS Caremark has, with the knowing and willful participation and assistance of each Manufacturer Defendant, engaged in hidden profit-making schemes falling into four general categories: (1) garnering undisclosed Manufacturer Payments from each Manufacturer Defendant that CVS Caremark retains to a large extent; (2) generating substantial profits from pharmacies because of the falsely inflated prices; (3) generating profits on the diabetes medications sold through CVS Caremark's own mail-order and retail pharmacies; and (4) keeping secret discounts each Manufacturer Defendant provides in association with CVS Caremark's mail-order and retail operations.



537. At all relevant times, CVS Caremark and each Manufacturer Defendant has been aware of its respective Manufacturer–PBM Enterprise’s conduct, has been a knowing and willing participant in and coordinator of that conduct and has reaped profits from that conduct.

538. Neither CVS Caremark nor any of the Manufacturer Defendants alone could have accomplished the purposes of the Manufacturer–PBM Enterprises without the other entities.

**C. The Enterprises Misrepresent and Fail to Disclose Material Facts in Furtherance of the Insulin Pricing Scheme**

539. Each Manufacturer–PBM Enterprise knowingly made material misrepresentations to the public and the Plaintiff in furtherance of the Insulin Pricing Scheme, including publishing artificially inflated prices for insulin on published indices and representing that:

- a. the false list prices for the at-issue diabetes medications were reasonably related to the actual prices realized by Defendants and were a reasonable and fair basis on which to base the price Plaintiff paid for these drugs;
- b. each Manufacturer priced its at-issue drugs according to each drug’s value to the healthcare system and the need to fund innovation;
- c. the Manufacturer Payments paid back to CVS Caremark for each at-issue drug were for Plaintiff’s benefit;
- d. all “rebates” and discounts negotiated by CVS Caremark with the Manufacturer Defendants were remitted to Plaintiff;
- e. the “rebates” negotiated by the members of each enterprise saved Plaintiff money;

- f. each Manufacturer Defendant and CVS Caremark were transparent with Plaintiff regarding the Manufacturer Payments and the PBMs did not retain any funds associated prescription drug rebates or the margin between guaranteed reimbursement rates and the actual amount paid to the pharmacies; and
- g. CVS Caremark constructed formularies in a manner that lowered the price of the at-issue drugs and promoted the health and safety of diabetics.

540. Each false list price published by the Manufacturer Defendants constituted a material misrepresentation to Plaintiff and the public, in that each purported to be a fair market price for an at-issue drug, and each omitted to disclose the fraudulent spread between the list price and the net price of the medication or the basis therefor. Specific examples of such misrepresentations are set forth in Table 1 and Figures 3-11. Examples of other specific affirmative representations by each RICO Defendant in furtherance of each enterprise's Insulin Pricing scheme are set forth in paragraphs 416-429, 433-437, 440-461, and 465-478.

541. At all times relevant to this Complaint, each Manufacturer–PBM Enterprise knew the above-described representations to be false.

542. At all times relevant to this Complaint, each Manufacturer–PBM Enterprise intentionally made these representations for the purpose of inducing Plaintiff into paying artificially inflated prices for diabetes medications.

543. Plaintiff relied on the material misrepresentations and omissions made by each Manufacturer–PBM Enterprise in paying prices for the at-issue diabetes medications based upon the false prices generated by Insulin Pricing Scheme.

544. Additionally, each PBM–Manufacturer Enterprise relied on the list prices negotiated and published by the other PBM–Manufacturer enterprises in setting their own list prices and determining the value of the kickbacks paid to the PBMs. Plaintiff was injured by the inflated prices that arose as a result.

545. CVS Caremark convinced Plaintiff to pay prices for the at-issue drugs based on the false list price by using the misrepresentations listed above to convince Plaintiff that they had secured lower prices when, in fact, they did the opposite, all while concealing the Insulin Pricing Scheme.

546. Without these misrepresentations and each RICO Defendant’s failure to disclose the Insulin Pricing Scheme, each Manufacturer–PBM Enterprise could not have achieved its common purpose, as Plaintiff would not have been willing to pay these false list prices.

**D. Defendants’ Use of the U.S. Mails and Interstate Wire Facilities**

547. Each of the Manufacturer–PBM Enterprises engaged in and affected interstate commerce because each engaged in the following activities across state boundaries: the sale, purchase and/or administration of diabetes medications; the setting and publishing of the prices of these drugs; and/or the transmission of pricing information of diabetes medications; and/or the transmission and/or receipt of sales and marketing literature; and/or the transmission of diabetes medications through mail-order and retail pharmacies; and/or the transmission and/or receipt of invoices, statements, and payments related to the use or administration of diabetes medications; and/or the negotiations and transmissions of contracts related to the pricing of and payment for diabetes medications.

548. Each Manufacturer–PBM Enterprise participated in the administration of diabetes medications to millions of individuals located throughout the United States, including in Cleveland and elsewhere in this District.

549. Each Manufacturer Defendant’s and CVS Caremark’s illegal conduct and wrongful practices were carried out by an array of employees, working across state boundaries, who necessarily relied upon frequent transfers of documents and information and products and funds through the U.S. mails and interstate wire facilities.

550. The nature and pervasiveness of the Insulin Pricing Scheme, which included each Manufacturer Defendant’s and CVS Caremark’s corporate headquarters operations, necessarily required those headquarters to communicate directly and frequently by the U.S. mails and by interstate wire facilities with each other and with pharmacies, physicians, payors, and diabetics in Cleveland and throughout Ohio.

551. Each Manufacturer–PBM Enterprise’s use of the U.S. mails and interstate wire facilities to perpetrate the Insulin Pricing Scheme involved thousands of communications including:

- a. marketing materials about the published prices for diabetes medications, which each Manufacturer Defendant sent to CVS Caremark located across the country, in Cleveland, and throughout Ohio;
- b. written and oral representations of the false list prices of diabetes medications that each Manufacturer Defendant and CVS Caremark made at least annually and, in many cases, several times during a single year to the public;
- c. thousands of written and oral communications discussing, negotiating, and confirming the placement of each Manufacturer Defendant’s diabetes medications on CVS Caremark’s formularies;

- d. written and oral representations made by each Manufacturer Defendant regarding information or incentives paid back to CVS Caremark for each diabetes medication sold and/or to conceal these incentives or the Insulin Pricing Scheme;
- e. written communications made by each Manufacturer Defendant, including checks, relating to Manufacturer Payments paid to CVS Caremark to persuade it to advocate the at-issue diabetes medications;
- f. written and oral communications with U.S. government agencies that misrepresented what the published prices were or that were intended to deter investigations into the true nature of the published prices or to forestall changes to reimbursement based on something other than published prices;
- g. written and oral communications with payors, including the Plaintiff, regarding the price of diabetes medications;
- h. written and oral communications to the Plaintiff, including marketing and solicitation material sent by CVS Caremark regarding the existence, amount, or purpose of payments made by each Manufacturer Defendant to CVS Caremark for the diabetes medications described herein and the purpose of CVS Caremark's formularies;
- i. transmission of published prices to third parties and payors, including the Plaintiff; and
- j. receipts of money on tens of thousands of occasions through the U.S. mails and interstate wire facilities—the wrongful proceeds of the Insulin Pricing Scheme.

552. Although Plaintiff pleads the dates of certain communications in allegations incorporated into this Count, it cannot allege the precise dates of others

without access to books and records within each RICO Defendant's exclusive custody and control. Indeed, an essential part of the successful operation of the Insulin Pricing Scheme depended upon secrecy, and each Manufacturer Defendant and CVS Caremark took deliberate steps to conceal its wrongdoing.

**E. Conduct of the Manufacturer–PBM Enterprises' Affairs**

553. Each Manufacturer Defendant and Express Scripts and OptumRx participates in the operation and management of Manufacturer–PBM Enterprises with which it is associated and, in violation of Section 1962(c) of RICO, and conducts or participates in the conduct of the affairs of those association-in-fact RICO enterprises, directly or indirectly. Such participation is carried out in the following ways:

- a. Each Manufacturer Defendant directly controls the secret Manufacturer Payments it provides to CVS Caremark for its diabetes medications.
- b. CVS Caremark directly manages and controls its drug formularies and the placement of the at-issue diabetes medications on those formularies.
- c. CVS Caremark intentionally selects higher-priced diabetes medications for formulary placement and exclude lower priced ones in order to generate larger profits and they coordinate with the Manufacturer Defendants to increase the availability and use of higher-priced medications because they are more profitable for both groups of Defendants.
- d. Each Manufacturer Defendant directly controls the publication of the false list prices generated by the Insulin Pricing Scheme.
- e. Each Manufacturer Defendant directly controls the creation and distribution of marketing, sales and other materials used to inform CVS Caremark of the profit potential from its diabetes medications.

- f. CVS Caremark directly controls the creation and distribution of marketing, sales and other materials used to inform payors and the public of the benefits and cost-saving potential of CVS Caremark's formularies and negotiations with the Manufacturers.
- g. CVS Caremark directs and controls each enterprise's direct relationships with payors such as the Plaintiff by negotiating the terms of and executing the contracts that govern those relationships.
- h. CVS Caremark directs and controls each enterprise's Insulin Pricing Scheme by hiding, obfuscating, and laundering Manufacturer Payments through their affiliated entities in order to retain a large and undisclosed proportion of the Manufacturer Payments to the detriment of payors, including Plaintiff.
- i. CVS Caremark distributes through the U.S. mail and interstate wire facilities, promotional and other materials that claim the Manufacturer Payments paid from each Manufacturer Defendant to CVS Caremark save Plaintiff and other payors money on the at-issue drugs.
- j. Each Manufacturer Defendant represented to the Plaintiff—by publishing and promoting false list prices without stating that these published prices differed substantially from the prices realized by each Manufacturer Defendant and CVS Caremark—that the published prices of diabetes medications reflected or approximated the actual price realized by Defendants and resulted from transparent and competitive, fair market forces.

**F. Defendants' Pattern of Racketeering Activity**

554. Each Manufacturer Defendant and CVS Caremark has conducted and participated in the affairs of their respective Manufacturer-PBM Enterprises through a

pattern of racketeering activity, including acts that are unlawful under 18 U.S.C. § 1341, relating to mail fraud, and 18 U.S.C. § 1343, relating to wire fraud.

555. Each Manufacturer Defendant's and CVS Caremark's pattern of racketeering involved thousands, if not hundreds of thousands, of separate instances of use of the U.S. mails or interstate wire facilities in furtherance of the Insulin Pricing Scheme. Each of these mailings and interstate wire transmissions constitutes a "racketeering activity" within the meaning of 18 U.S.C. § 1961(1). Collectively, these violations constitute a "pattern of racketeering activity," within the meaning of 18 U.S.C. § 1961(5), in which each Manufacturer Defendant and CVS Caremark intended to defraud Plaintiff.

556. By intentionally and falsely inflating the list prices, by misrepresenting the purpose behind both the Manufacturer Payments made from each Manufacturer Defendant to CVS Caremark and CVS Caremark's formulary construction, and by subsequently failing to disclose such practices to Plaintiff, each Manufacturer Defendant and CVS Caremark engaged in a fraudulent and unlawful course of conduct constituting a pattern of racketeering activity.

557. Each Manufacturer Defendant's and CVS Caremark's racketeering activities amounted to a common course of conduct, with similar patterns and purposes, intended to deceive Plaintiff.

558. Each separate use of the U.S. mails and/or interstate wire facilities employed by each Manufacturer Defendant and CVS Caremark was related, had similar intended purposes, involved similar participants and methods of execution, and had the same results affecting the same victims, including Plaintiff.

559. Each Manufacturer Defendant and CVS Caremark engaged in the pattern of racketeering activity for the purpose of conducting the ongoing business affairs of the



respective Manufacturer–PBM Enterprises with which each of them is and was associated in fact.

**G. The RICO Defendants’ Motive**

560. Each Manufacturer Defendant’s and CVS Caremark’s motive in creating and operating the Insulin Pricing Scheme and conducting the affairs of the Manufacturer–PBM Enterprises described herein was to control the market for diabetes medications and falsely obtain sales of and profits from diabetes medications.

561. The Insulin Pricing Scheme was designed to, and did, encourage others, including payors such as the Plaintiff, to advocate the use of each Manufacturer Defendant’s products and to pay for those diabetes medications based on a falsely inflated price. Each Manufacturer Defendant used the Insulin Pricing Scheme to obtain formulary placement to sell more of its drugs without cutting into its profits. CVS Caremark used the Insulin Pricing Scheme to falsely inflate the price payors such as the Plaintiff paid for diabetes medications in order to profit off the Insulin Pricing Scheme, as discussed above.

**H. The Manufacturer–PBM Enterprises’ Insulin Pricing Scheme Injured Plaintiff**

562. Each Manufacturer–PBM Enterprise’s violations of federal law and pattern of racketeering activity have directly and proximately caused the Plaintiff to be injured in its business or property.

563. The prices Plaintiff pays for the at-issue drugs are tied directly to the false list prices generated by the Insulin Pricing Scheme.

564. No other intermediary in the supply chain has control over or is responsible for the list prices on which nearly all Plaintiff’s payments are based other than the Manufacturer–PBM Defendant Enterprises.

565. Defendants collectively set the prices Plaintiff paid for the at-issue drugs.

566. During the relevant period, CVS Caremark provided PBM services to the Plaintiff and benefited therefrom.

567. During the relevant period, the Plaintiff paid CVS Caremark directly for the at-issue drugs.

568. Each Manufacturer–PBM Enterprise controlled and participated in the Insulin Pricing Scheme that was directly responsible for the false list prices upon which the price Plaintiff paid was based.

569. Plaintiff thus was damaged by the scheme. But for the misrepresentations and false prices created by the Insulin Pricing Scheme that each Manufacturer–PBM Enterprise employed, Plaintiff would have paid less for the medications.

570. While Defendants' scheme injured an enormous number of payors and plan members, Plaintiff's damages are separate and distinct from those of any other victim that was harmed by the Manufacturer–PBM Defendant Enterprises' Insulin Pricing Scheme.

571. By virtue of these violations of 18 U.S.C. § 1962(c), under the provisions of Section 1964(c) of RICO, Defendants are jointly and severally liable to the Plaintiff for three times the damages that were sustained, plus the costs of bringing this action, including reasonable attorneys' fees.

572. By virtue of these violations of 18 U.S.C. § 1962(c), under the provisions of Section 1964(a) of RICO, the Plaintiff seeks injunctive relief against each Manufacturer and CVS Caremark for their fraudulent reporting of their prices and their continuing acts to affirmatively misrepresent and/or conceal and suppress material facts concerning their false and inflated prices for diabetes medications, plus the costs of bringing this suit, including reasonable attorneys' fees.

573. Absent an injunction, the effects of this fraudulent, unfair, and unconscionable conduct will continue. Plaintiff continues to purchase the at-issue diabetes medications. Plaintiff will continue to pay based on the Defendants' false list prices. This continuing fraudulent, unfair, and unconscionable conduct is a serious matter that calls for injunctive relief as a remedy. The Plaintiff seeks injunctive relief, including an injunction against each Manufacturer and CVS Caremark, to prevent them from affirmatively misrepresenting and/or concealing and suppressing material facts concerning their conduct in furtherance of the Insulin Pricing Scheme.

**Count Two**

**Violations of RICO, 18 U.S.C. § 1962(d)  
By Conspiring to Violate 18 U.S.C. § 1962(c)  
(Against All Defendants)**

574. Plaintiff re-alleges and incorporates herein by reference all foregoing and subsequent fact allegations, including ¶¶ 1-573, 587-94, 597-610, and 616-626.

575. Section 1962(d) of RICO provides that it "shall be unlawful for any person to conspire to violate any of the provisions of subsection (a), (b) or (c) of this section."

576. Defendants have violated § 1962(d) by agreeing and conspiring to violate 18 U.S.C. § 1962(c). The object of this conspiracy has been and is to conduct or participate in the Insulin Pricing Scheme.

577. As set forth in detail above, as well as in the Civil Conspiracy count below, Defendants each knowingly agreed to facilitate the Insulin Pricing Scheme and each has engaged in numerous overt and predicate fraudulent racketeering acts in furtherance of the conspiracy. Specifically, Defendants agreed to and did inflate the prices of the at-issue drugs in lockstep to achieve an unlawful purpose; Defendants agreed to and did make false or misleading statements or material omissions regarding the reasons for these price

increases, the purpose of the Manufacturer Payments exchanged between Defendants and the PBMs' formulary construction; and PBMs agreed to and did, in concert, request and receive larger Manufacturer Payments and higher prices in exchange for formulary placement.

578. The nature of the above-described Defendant co-conspirators' acts, material misrepresentations, and omissions in furtherance of the conspiracy gives rise to an inference that they not only agreed to the objective of an 18 U.S.C. § 1962(d) violation of RICO by conspiring to violate 18 U.S.C. § 1962(c), but they were aware that their ongoing fraudulent and extortionate acts have been and are part of an overall pattern of racketeering activity.

579. Defendants have engaged and continue to engage in the commission of overt acts, including the following unlawful racketeering predicate acts:

- a. multiple instances of mail fraud in violations of 18 U.S.C. § 1341;
- b. multiple instances of wire fraud in violations of 18 U.S.C. § 1343; and
- c. multiple instances of unlawful activity in violation of 18 U.S.C. § 1952.

580. Defendants' conspiracy to violate the above federal laws and the effects thereof detailed above are continuing and will continue. Plaintiff has been injured in its property by reason of these violations: Plaintiff has paid more for the at-issue drugs than it would have but for Defendants' conspiracy to violate 18 U.S.C. § 1962(c).

581. By virtue of these violations of 18 U.S.C. § 1962(d), Defendants are jointly and severally liable to Plaintiff for three times the damages this District has sustained, plus the cost of this action, including reasonable attorneys' fees.

**Count Three**

**Ohio Deceptive Trade Practices Act, Ohio Revised Code Section 4165**  
(Against Defendants Eli Lilly, Novo Nordisk, Sanofi, and CVS Caremark)

582. Plaintiff re-alleges and incorporates herein by reference all foregoing and subsequent fact allegations, including ¶¶ 1-580, 597-610, and 616-26.

583. Plaintiff brings this claim against Defendants Eli Lilly, Novo Nordisk, Sanofi, and CVS Caremark (as defined in ¶ 110). All are referred to collectively throughout Count Three as “Defendants.” Eli Lilly, Novo Nordisk and Sanofi are referred to throughout Count Three as “Manufacturer Defendants.”

584. Defendants are “persons” as defined by Ohio Revised Code § 4165.01(D).

585. Plaintiff is a “person” as defined by Ohio Revised Code § 4165.01(D).

586. Defendants’ misconduct as described throughout this Complaint, collectively and as individuals, constitutes deceptive trade practices as defined in Ohio Revised Code § 4165.02(A).

587. Defendants are independently liable for their own misconduct in violation of the Deceptive Trade Practices Act and are liable for their collective efforts in furtherance of the Insulin Pricing Scheme. Using a complex structure of interdependent entities, Defendants confuse and mislead consumers about each Defendant’s respective role in an attempt to evade liability for the unfair and deceptive scheme as a whole, and for the acts and omissions of the enterprise’s interdependent participants.

588. Defendants’ misconduct in violation of the Deceptive Trade Practices Act includes the creation and implementation of the Insulin Pricing Scheme, which included:

- a. The Manufacturer Defendants published prices for the at-issue drugs and, in doing so, held these prices out as the actual prices for these drugs despite knowing these prices were artificially inflated and untethered from the cost of

the drugs or the price the Manufacturers were paid for them—all with CVS Caremark's knowledge, consent, and cooperation.

- b. The Manufacturer Defendants misrepresented and actively concealed the true reasons why they set and raised list prices—the truth being that it was to increase revenues and profits and to offer higher prices and larger Manufacturer Payments to CVS Caremark—all with CVS Caremark's knowledge, consent, and cooperation.
- c. CVS Caremark furthered the scheme by using the artificially inflated list prices to determine the inflated prices paid by payors, including Plaintiff and Plaintiff's Beneficiaries—all with the Manufacturer Defendants' knowledge, consent, and cooperation.
- d. CVS Caremark represented to payors, including Plaintiff, and to the public that it worked to generate savings with respect to the at-issue drugs and to promote the health of diabetics. Instead, directly counter to these representations, CVS Caremark drove up the prices of the at-issue drugs and damaged payors, including Plaintiff, by demanding ever-increasing Manufacturer Payments that, in turn, increased what otherwise would have been the retail prices for the at-issue drugs—all with the Manufacturer Defendants' knowledge, consent, and cooperation.
- e. CVS Caremark has hidden, obfuscated, and laundered these Manufacturer Payments through their affiliated entities in order to retain a large and undisclosed proportion of the Manufacturer Payments to the detriment of payors, including Plaintiff.
- f. CVS Caremark intentionally selected higher-priced diabetes medications for

formulary placement and excluded lower priced ones in order to generate larger profits and coordinated with the Manufacturer Defendants to increase the availability and use of higher priced medications because they are more profitable for both groups of Defendants.

- g. CVS Caremark misled its payors, including Plaintiff, as to the true nature of value of the services they provided and reaped illicit profits exponentially greater than the fair market value of the services they purported to provide—all with the Manufacturer Defendants' knowledge, consent, and cooperation.
- h. CVS Caremark owed a duty to disclose the true facts to their payor clients, including Plaintiff, but intentionally chose instead to conceal them, both to further the Insulin Pricing Scheme and to conceal it from payors, including Plaintiff—all with the Manufacturer Defendants' knowledge, consent, and cooperation.

589. By together carrying out and concealing the Insulin Pricing Scheme, as described herein, Defendants engaged in deceptive trade practices under the Deceptive Trade Practices Act, including, but not limited to:

- a. representing that goods or services have characteristics and benefits that they do not have, Ohio Rev. Code § 4165.02(A)(7);
- b. representing that services are of a particular standard, quality or grade, if they are another, § 4165.02(A)(9);
- c. advertising goods and services with the intent not to sell them as advertised, Ohio Rev. Code § 4165.02(A)(11); and
- d. making false and misleading statements of fact concerning the reasons for, existence of, or amounts of price reductions, Ohio Rev. Code § 4165.02(A)(12):

- A characteristic of every commodity in Ohio economy is its price, which is represented by every seller to every buyer that the product being sold is being sold at a legal, competitive, and fair market value.
- The Manufacturer Defendants reported and published artificially inflated list prices for each at-issue drug and, in doing so, represented that the reported prices were reasonably related to the net prices for the at-issue drugs and otherwise reflected the fair market value for the drugs—all with CVS Caremark’s knowledge, consent, and cooperation.
- CVS Caremark misrepresented to payors and the public that their formularies and the portion of the Manufacturer Payments they disclosed have the characteristic and benefit of lowering the price of the at-issue drugs and promoting diabetics’ health when, in fact, the opposite is true.
- CVS Caremark utilized the artificially inflated price—which they are directly responsible for inflating and which they know is untethered from the actual price—to make false and misleading statements regarding the amount of savings the PBMs generate for payors and the public.
- Defendants made false and misleading representations of fact that the prices for the at-issue diabetes medications were legal, competitive, and fair market value prices.
- At no point did the Defendants reveal that the prices for the at-issue drugs were not legal, competitive or at fair market value—rather, they coordinated to overtly mislead the public and payors, including Plaintiff, and undertook a concerted effort to conceal the truth.
- At no point did these Defendants disclose that the prices associated with the at-issue drugs were generated by the Insulin Pricing Scheme—rather, they overtly misled the public and payors, including Plaintiff, and undertook a concerted effort to conceal the truth.
- At least once a year for each year during the relevant period, Defendants reported and published false prices for each at-issue drug and in doing so represented that the list prices were the actual, legal and fair prices for these drugs and resulted from competitive market forces when they knew that was not true.
- In addition, by granting the at-issue drugs preferred formulary position—formulary positions that CVS Caremark represents are reserved for reasonably priced drugs and that are meant to promote cost savings and the health of diabetics— CVS Caremark knowingly and purposefully utilized the false prices that were generated by the Insulin Pricing Scheme—all with the Manufacturer Defendants knowledge, consent, and cooperation.



- By granting the at-issue diabetes medications preferred formulary positions, CVS Caremark ensured that prices generated by the Insulin Pricing Scheme would harm Plaintiff—all with the Manufacturer Defendants knowledge, consent, and cooperation.
- CVS Caremark also misrepresented that its formularies promoted the cost-savings to Plaintiff.
- Defendants' representations are false and Defendants knew they were false when they were made. Defendants knew that the prices they reported and utilized are artificially inflated for the purpose of maximizing revenues and profits pursuant to the Insulin Pricing Scheme.
- These Defendants not only knew that CVS Caremark's formulary construction fueled the precipitous price increases that damaged Plaintiff's financial well-being, but coordinated in ways that made such harm inevitable—all for the sole purpose of generating more revenues and profits for both groups of Defendants.
- Defendants affirmatively withheld this truth from Plaintiff, even though these Defendants knew that the Plaintiff's intention was to pay the lowest possible price for diabetes medications and expectation was to pay a legal, competitive price that resulted from transparent market forces.
- Defendants made false and misleading misrepresentations of fact related to the Manufacturer Payments and the negotiations that occurred between CVS Caremark and the Manufacturer Defendants.
- CVS Caremark knowingly made false and misleading statements concerning the reasons for, existence of, and amount of price reductions by misrepresenting that the Manufacturer Payments lower the overall price of diabetes medications and reduce payor costs while promoting the health of diabetics.
- These representations were false and Defendants knew they were false when they were made. CVS Caremark knew that the Manufacturer Payments were not reducing the overall price of diabetes medications but rather are an integral part of the secret Insulin Pricing Scheme and are responsible for the inflated prices.
- CVS Caremark owed a duty to disclose the true facts to their payor clients, including Plaintiff, but intentionally chose instead to conceal them, both to further the Insulin Pricing Scheme and to conceal it from payors, including Plaintiff—all with the intent of misrepresenting the characteristics and benefits of their services and the existence and nature of purported price reductions they obtained for payors, including Plaintiff. All of this was done with the Manufacturer Defendants' knowledge, consent, and cooperation.

- Defendants continue to make these misrepresentations and to publish prices generated by the Insulin Pricing scheme, and Plaintiff continues to purchase diabetes medications at inflated prices.

590. Defendants' deceptive acts and practices were intended to deceive, actually deceived, and had the tendency to deceive payors, including Plaintiff.

591. Defendants' deception was material in that it was likely to influence (and did influence) the purchasing decisions of payors, including Plaintiff.

592. Defendants' deceptive acts and practices—including their concealment and suppression of material facts—were carried out with the intent that Plaintiff, among others, would rely upon them in the course of trade or commerce, which Plaintiff reasonably did, proximately causing actual economic damage to Plaintiff.

593. Defendants' deceptive acts and practices were carried out knowingly and in willful, wanton, and reckless disregard for the economic and physical well-being of others. Defendants' deceptive acts and practices are reprehensible not only for their impact upon Plaintiff and other payors, but because they posed a grave risk of physical harm to others who are not parties to this lawsuit.

594. The acts and practices alleged herein are ongoing, repeated, and affect the public interest.

595. Accordingly, Plaintiff seeks actual economic damages, punitive damages, injunctive relief, attorneys' fees, costs of this action, all appropriate penalties and fees, and any other relief to which Plaintiff may be entitled.

#### **Count Four**

#### **Civil Conspiracy (Against all Defendants)**

596. Plaintiff re-alleges and incorporates by reference all foregoing and subsequent fact allegations, including ¶¶ 1-580, 587-94, and 616-626.

597. Defendants' conduct described throughout this Complaint as comprising and implementing the Insulin Pricing Scheme constituted a combination of two or more persons created and carried out for an unlawful purpose or a lawful purpose by unlawful means, further to which one or all Defendants committed an overt tortious or unlawful act.

598. Each and every Defendant knowingly and maliciously participated in the creation and implementation of the Insulin Pricing Scheme.

599. Each and every Defendant planned, assisted, and encouraged the Insulin Pricing Scheme.

600. Defendants aided and abetted one another to violate federal laws and the Ohio Deceptive Practices Act, as alleged herein.

601. Each Defendant agreed to carry out and carried out overt acts in furtherance of the Insulin Pricing Scheme that artificially inflated the price of diabetes medications to Plaintiff's detriment.

602. Each PBM Defendant made a conscious commitment to participate in the Insulin Pricing Scheme.

603. The Manufacturer Defendants agreed with each other and PBM Defendants to intentionally raise their diabetes medication prices and then pay back a significant portion of those prices to the PBMs.

604. In exchange for Manufacturer Defendants' inflating their prices and making large secret payments, the PBM Defendants agreed to and did grant preferred formulary status to the Manufacturer Defendants' diabetes medications.

605. Each Defendant shares a common purpose of perpetuating the Insulin Pricing Scheme and neither the PBM Defendants nor the Manufacturer Defendants alone could have accomplished the Insulin Pricing Scheme without their co-conspirators.

606. The PBM Defendants need the Manufacturer Defendants to inflate the list price of their diabetes medications and to make secret payments back to the PBM Defendants in order for the PBM Defendants to profit off the Insulin Pricing Scheme.

607. The Manufacturer Defendants need the PBM Defendants to grant certain diabetes medications preferred formulary placement in order to maintain access to payors and diabetics whose purchase of the at-issue drugs generated unearned and unwarranted revenue for all Defendants.

608. As discussed throughout this Complaint, the Insulin Pricing Scheme resulted from explicit agreements, direct coordination, constant communication and exchange of information between the PBMs and the Manufacturers.

609. In addition to the preceding direct evidence of an agreement, Defendants' conspiracy is also demonstrated by the following indirect evidence that infers Defendants conspired to engage in fraudulent conduct:

- a. Defendants refuse to disclose the details of their pricing structures, agreements and sales figures in order maintain the secrecy of the Insulin Pricing Scheme;
- b. Numerous ongoing government investigations, hearings, and inquiries have targeted the Insulin Pricing Scheme and the collusion between the Manufacturer and PBM Defendants, including:
  - civil investigative demands to the Manufacturers from the States of California, Florida, Minnesota, and Washington relating to the pricing of their insulin products and their relationships with the PBM Defendants;
  - letters from numerous senators and representatives in recent years to the Justice Department and the Federal Trade Commission asking them to investigate potential collusion among Defendants;

- 2019 hearings before the House Oversight and Reform Committee on industry practices; and
  - the Senate Finance Committee’s recent two-year probe into the Insulin Pricing Scheme and the conspiracy between the Manufacturers and the PBMs, resulting in the Grassley-Wyden report, first published in 2021.
- c. The astronomical rise in the price of the at-issue drugs coincides with PBM Defendants’ rise within the pharmaceutical pricing system starting in 2003.

610. Plaintiff was damaged and continues to be damaged by the conspiracy when it overpaid for the diabetes medications as result of Defendants’ unlawful actions.

### **Count Five**

#### **Unjust Enrichment**

(Against Defendants Eli Lilly, Novo Nordisk, Sanofi, and CVS Caremark)

611. Plaintiff re-alleges and incorporates herein by reference all foregoing fact allegations, including ¶¶ 1-580, 587-94, and 597-610.

612. Plaintiff brings this claim against Defendants Eli Lilly, Novo Nordisk, Sanofi, and CVS Caremark (as defined collectively in ¶ 110). All are referred to collectively throughout Count Five as “Defendants.”

613. This claim is alleged in the alternative to Plaintiff’s claims for legal relief.

614. It is a fundamental principle of fairness and justice that a person should not be unjustly enriched at the expense of another.

615. A person should not be unjustly enriched at the expense of another even if that person’s conduct is not tortious.

616. Defendants jointly and severally deceived Plaintiff and have received a financial windfall from the Insulin Pricing Scheme at Plaintiff’s expense.

617. Plaintiff unknowingly conferred this benefit upon Defendants to Plaintiff’s financial detriment.

618. Defendants, jointly and severally, wrongfully secured and retained a benefit in the form of amounts paid for diabetes medications, unearned fees and other payments collected based on the market forces and prices generated by the Insulin Pricing Scheme, and revenues that would not have been realized but for the Insulin Pricing Scheme.

619. Defendants, jointly and severally, wrongfully secured and retained a benefit in the form of revenues and profits to which they were not entitled, which did not represent the fair market value of the goods or services they offered, and which were obtained at Plaintiff's expense.

620. Defendants, jointly and severally, wrongfully secured and retained a benefit in the form of drug monies paid at prices that would not have existed but for the Defendants' misconduct.

621. Defendants were aware of the benefit, voluntarily accepted it, and retained and appreciated the benefit, to which they were not entitled, all at Plaintiff's expense.

622. Any Defendant's retention of any portion of any benefit obtained by way of the Insulin Pricing Scheme is unjust and inequitable regardless of the Insulin Pricing Scheme's legality.

623. Each and every Defendant's retention of any portion of the benefit violates the fundamental principles of justice, equity, and good conscience. Even absent Plaintiff's ability to prove the elements of any other claim, it would be unfair, unjust, and inequitable for any Defendant to retain any portion of the benefit.

624. Even absent legal wrongdoing by any or all Defendants, Plaintiff has a better claim to the benefit than any and all Defendants.

625. The benefit retained is in an amount not less than the difference between the reasonable or fair market value of the at-issue drugs for which Plaintiff paid and the actual

value of the at-issue drugs these Defendants delivered and, as to the CVS Caremark, the reasonable or fair market value of the services for which Plaintiff paid and the actual value of services rendered with respect to the at-issue drugs.

626. Defendants should not be permitted to retain the benefit conferred upon them by Plaintiff and restitution is appropriate to prevent the unjust enrichment.

627. Accordingly, Plaintiff seeks disgorgement of the benefit and restitution, rescission, or such other relief as will restore to Plaintiff that to which it is entitled.

## **VII. MOTION FOR INJUNCTION**

628. Plaintiff re-alleges and incorporates herein by reference all foregoing fact allegations, including ¶¶ 1-580, 587-94, 597-610, and 616-626.

629. By Defendants' violations of RICO, the Ohio Deceptive Practices Act, and the common law, Plaintiff has suffered, and will continue to suffer, immediate and irreparable injury, loss, and damage, as discussed herein.

630. The ongoing and threatened injury to Plaintiff and its Beneficiaries outweighs the harm that an injunction might cause Defendants.

631. As a direct and proximate result of the conduct of the Defendants in committing the above and foregoing acts, Plaintiff moves this Court for injunctive relief against the Defendants pursuant the Ohio Deceptive Trade Practices Act (Ohio Revised Code § 4165.01 *et seq.*) and 18 U.S.C. § 1964(a), thereby enjoining Defendants from committing future violations of the Ohio Deceptive Trade Practices Act and RICO.

632. An injunction is consistent with the public interest because it will protect the health and economic interests of Plaintiff and the integrity of the Ohio marketplace.

### VIII. PRAYER FOR RELIEF

WHEREFORE, Plaintiff The City of Cleveland, Ohio prays for entry of judgment against the Defendants for all the relief requested herein and to which the Plaintiff may otherwise be entitled, specifically including, but without limitation, to-wit:

A. A determination that Defendants have violated Ohio Deceptive Trade Practices Act, have violated RICO, have been unjustly enriched, and have engaged in a civil conspiracy;

B. Judgment in favor of Plaintiff and against the Defendants for damages in excess of the minimum jurisdictional requirements of this Honorable Court, in a specific amount to be proven at trial;

C. Injunctive relief in accordance with the Ohio Deceptive Trade Practices Act (Ohio Revised Code § 4165.01 *et seq.*) and 18 U.S.C. § 1964(a), to the effect that Defendants, their affiliates, successors, transferees, assignees, and the officers, directors, partners, agents, and employees thereof, and all other persons acting or claiming to act on their behalf or in concert with them, be enjoined and restrained from in any manner continuing, maintaining or renewing the conduct, contract, conspiracy or combination alleged herein in violation of the Ohio law and RICO, or from entering into any other contract, conspiracy or combination having a similar purpose or effect, and from adopting or following any practice, plan, program or device having a similar purpose or effect;

D. That Plaintiff:

- i. be awarded restitution, damages, disgorgement, penalties, and all other legal and equitable relief to which Plaintiff may be entitled;



- ii. be awarded punitive damages because Defendants knowingly, willfully, wantonly, and intentionally harmed the health, well-being, and financial interests of Plaintiff and its Beneficiaries;
- iii. be awarded pre- and post-judgment interest as provided by law, and that such interest be awarded at the highest legal rate from and after the date of service of the initial Complaint in this action;
- iv. recover its costs of this action, including its reasonable attorneys' fees; and
- v. be awarded such other further relief as the case may require and the Court may deem just and proper under the circumstances.

### IX. JURY DEMAND

Plaintiff demands trial by jury on all issues so triable.

Dated: July 24, 2023.

/s/Shawn Acton

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